EXHIBIT 69

SUBMITTED UNDER SEAL

CONFIDENTIAL

Volume I
Pages 1 to 222
Exhibits 1 - 18

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BRIANNA BOE, et al., Plaintiffs, UNITED STATES OF AMERICA, Intervenor Plaintiff,	:	
vs.	:	Civil Action No. 2:22-cv-184-LCB
HON. STEVE MARSHALL, in his official capacity as Attorney General of the State of Alabama, et al. Defendants.	:	

CONFIDENTIAL DEPOSITION OF JENIFER LIGHTDALE, M.D., a witness called on behalf of the Defendants, taken pursuant to the Federal Rules of Civil Procedure before Carol H. Kusinitz, Registered Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Offices of Holland & Knight, LLP, 10 St. James Avenue, Boston, Massachusetts, on Monday, May 6, 2024, commencing at 9:12 a.m.

APPEARANCES ON PAGE 2

PRESENT:

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Also Present: Shannon Minter, Esq. (Via Zoom)

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I N D E X

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E X H I B I T S

E X H I B I T S (Continued)

E X H I B I T S (Continued)

E X H I B I T S (Continued)

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P R O C E E D I N G S

JENIFER LIGHTDALE, M.D.

a witness called for examination by counsel for the Defendants, having been satisfactorily identified by the production of her driver's license and being first duly sworn by the Notary Public, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. BROOKS:

Q. Dr. Lightdale, good morning.

Let me start by making sure that I understand the scope of the expertise that you're bringing to the table.

You're not a psychiatrist, correct?

A. I am not a psychiatrist.

Q. Nor a psychologist?

A. No.

Q. You don't have any degree relating to psychology?

A. No.

Q. You're not an expert in adolescent developmental psychology?

A. No.

Q. Or indeed adolescent anything, correct?

A. Correct.

Q. You're not an expert in neurology or cognition?

A. No.

Q. Do you have any publications relating to mental health at all?

A. Yes. I think somewhere back there there's something about kids with IBD and going to college. That's, like, maybe ten years ago. I worked with a fellow.

Q. Do you have any expertise at all relating to gender dysphoria or gender identity?

A. No.

Q. Have you ever diagnosed any patient with gender dysphoria?

A. No.

Q. Have you ever treated a patient for anything who, to your knowledge, suffered from gender dysphoria?

A. Yes.

Q. But your treatment had nothing to do with the gender dysphoria?

A. Correct.

Q. All right. Do you consider yourself to be

an expert in medical ethics?

A. No.

Q. You've never taught a course in medical ethics?

A. No.

Q. And other than a basic medical school course, have you had any special training in medical ethics?

A. Yes. As part of conducting research, you have to get trained in responsible conduct of research. So I have done that.

Q. You did not have any role at all in the development of the WPATH Standards of Care Version 8, did you?

A. No.

Q. Nor any version of the WPATH Standards of Care?

A. No.

Q. And you weren't, at any stage, invited to review or comment on a draft?

A. No.

Q. Do you have any knowledge of who comprises the membership of WPATH?

A. No.

Q. Do you have any knowledge of the process that was used to develop the WPATH SOC-8 other than the methodology web page you refer to in your expert report?
A. No. Just the web page.
Q. And you're not a member of the Endocrine Society, correct?
A. No.
Q. And do you have any knowledge at all as to the policies or procedures followed by any gender clinic in Alabama?
A. No.
MR. BROOKS: Let me ask the reporter to mark as Exhibit 1 an article from 2022 with such a long title, "Pediatric Endoscopy Quality Improvement Network Quality Standards," and it goes on from there, of which Dr. Lightdale is the first author.
(Document marked as Lightdale Exhibit 1 for identification)
Q. Dr. Lightdale, is this in fact a paper of which you are the lead author?
A. Yes.
Q. And can you generally describe for the record what this paper is.

A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy.
Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it refers to AGREE II.
Can you explain what AGREE II is.
A. Yes. So AGREE II, in my words, when I talk about it, is a framework or it's basically a way that you can decide that a guideline has been developed in a methodologically sound way. And so it's basically something you use, frankly, usually after the fact. But in our case, we said, "Let's start using it right away and say we're going to

follow the AGREE II methodology to actually develop our guidelines."
Q. So let me break that into two halves. I think what you first said is that AGREE II, what its primary function is is a methodology to evaluate -- maybe "quality" is not the right word, but the quality of a set of clinical practice guidelines; is that right?
A. Yeah. I wouldn't say "quality" is the right word. It is a way to look at how guidelines are developed and to really say that they met certain steps. And, you know, you can think of it as a strategy, you can think of it as a framework, and it's a way of assessing the guidelines.
Q. Assessing them with -- for what purpose? That is, are you trying to find out their reliability? You said "quality" isn't the right word, but assessment towards what end?
A. So basically it is, in the end they want to appraise the guidelines and to say did they meet certain points of developing it.
You know -- yeah.
Q. But the purpose isn't simply to award a gold star. The purpose is to give clinicians some

comfort that these guidelines are reliable; am I correct?
A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C.
Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct?
A. Yeah. We work as a group -- again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II gave us a framework to work in.
Q. All right.
MR. BROOKS: I'm going to ask the reporter to mark as Exhibit 2 a document entitled "AGREE II Instrument" dated December 2017.
(Document marked as Lightdale Exhibit 2 for identification)

Page 14

Q. And let me ask you first to take a look at this and identify it for the record, if you can.
A. Sure. This looks like a pdf of the AGREE II, what they call the Instrument.
Q. And explain to me what the Instrument -- what the AGREE Instrument is.
A. So I can't say I'm completely familiar with this exact, you know, document, but an instrument is essentially a tool you can use to apply something. So I presume it's something to apply to AGREE II.
Q. And it says that it's put out by The AGREE Next Steps Consortium. Is that a group or a name that means anything to you?
A. Not exactly. So I think AGREE is something I was aware of. And then what was more important for me is it was updated, and it's been updated now -- that's why it's now AGREE II -- and this update was actually 2017.
And why that's relevant is this thing that we talked about before was actually started in, like, 2018. So everybody was talking about AGREE II as, you know, a way that used a framework.
Q. Okay. Let me ask you to turn in this document -- and this is unusual -- turn to Page 0,

Page 15

if you would.
A. Okay. Is it 0, like, right there?
Q. No, it's not the first page. The first page of text is labeled 0.
A. Oh, I see. You go past the Roman numerals? Okay. Got it.
Q. And there, in the first paragraph, this document has a little subsection headed "Purpose of the AGREE II Instrument." And that indicates that clinical practice guidelines are, quote, "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."
Do you see that?
A. Yes, I do.
Q. And is it consistent with your understanding that the purpose of clinical practice guidelines is to assist practitioner and patient decisions?
A. Yes.
Q. And that those are to be systematically developed?
A. I mean, yes. I think we want good guidelines. So systematically is, you know, the

Page 16

concept of you do it in a good way, yes.
Q. And we'll talk more about what that means.
A. Okay.
Q. In the second paragraph, the last sentence says, "The quality of guidelines can be extremely variable and some often fall short of basic standards."
Do you see that language?
A. Yes.
Q. And is that consistent with your own observation in your professional life?
A. Yes.
Q. That is, you have seen many documents that claim to be clinical practice guidelines that fall short of basic standards?
A. No, I wouldn't say that. I would say I've been in the field of medicine longer than guidelines have been around. And so you've watched an evolution in how guidelines come about, what we actually are ready to consider a clinical practice guideline, if you will.
And this -- again, there's been a lot of evolution around this, but there's an effort to try to make sure that we have defined this in some way.

Page 17

So that -- which it wasn't. Like, in 2010 there was really very little definition. Certainly in 2000 there was almost no definition.
Q. And are you prepared to testify that, as of today, that clinical practice guidelines that are being created recently are uniformly of good quality?
A. No. They're still not of uniform good quality. But I think they're being held to a different standard. There is now a sense of one needs to go into a guideline with a methodology behind producing the guideline. And that wasn't the case for many years. So...
Q. During those many years, on what basis were guidelines created, if not using a systematic methodology?
A. So in -- I mean, I was in medical school from 1991 to 1995, and best practice was expert derived, like somebody said, "Here's the best way to do it," and everyone said "Okay." And we really -- really that's not the way you decide what is evidence, right? So the concept of evidence-based medicine is really 1995-ish.
Q. Look at the third paragraph on this Page 0.

Page 18

And the second sentence in that third paragraph reads, quote, "To that end, the AGREE instrument is a tool that assesses the methodological rigour and transparency in which a guideline is developed."

Do you understand the distinction being made between methodological rigour and transparency?

A. Yes.

Q. And do you understand those to be two key aspects of an appropriate method of developing a guideline?

A. So there are two components that need to be considered when developing a guideline, is the way I think of it.

Q. Those being rigour and transparency?

A. Methodology, rigour -- I mean, you could put those two together, but you need a methodology and you need transparency when you develop a guideline.

Q. All right. If we look on the second page -- this is a European document. I see the spelling, and they seem to have numbered their pages like they number the floors on an elevator.

So if you look at the second page, numbered 1, there is table that says, "Comparison of the

Page 19

Original AGREE and AGREE II items." Do you see that?

A. Yes.

Q. And down a little more than halfway through the table is a section headed "Domain 3. Rigour of Development." Do you see that?

A. Uh-huh.

Q. And under that are, in the "AGREE II" column, seven categories or items that are indicated. Do you see that?

A. You're talking in this column here (indicating)?

Q. Yes.

A. Okay.

Q. Just take a moment and look at it. You'll see that the first column is "Original AGREE Item," and the second is the revised AGREE II set of criteria, right?

A. Yes.

Q. So back to where we were. "Rigour of Development" under the AGREE II column there are seven specific items under the -- pardon me. I'm turning over the page. There are eight specific items under the "Rigour of Development" for AGREE

Page 20

II; am I correct?

A. One, two, three, four, five, six, seven, eight, yes.

Q. Okay. And one of those is whether systematic methods were used to search for evidence, correct?

A. Can I just say, it's a little bit confusing, to be honest, because it's Number 8 to 14, so my math tells me it's six. I don't know why that is.

Q. It is because of the place that it says "New Item 9" is why. So the numbering is messed up.

A. Okay. Okay.

Q. I had miscounted myself for exactly the same reason.

But now we can put the numbering aside, perhaps, and one of the criteria for Rigour of Development is Line 8, "Systematic methods were used to search for evidence," correct?

A. Yes.

Q. And one is whether the criteria for selecting the evidence were clearly described, right?

A. Yes.

Page 21

Q. Looking at 11, whether the -- not only the health benefits, but side effects and risks have been considered in formulating the recommendations, right?

A. Yes.

Q. And whether there -- Item 12, one of the criteria of rigour is whether there is an explicit link between the recommendations and the supporting evidence. Do you see that?

A. Yes.

Q. And let me pause on that one for a moment. Why is it important that guidelines provide an explicit link between the recommendations and the supporting evidence?

A. I mean, the link might be that there is no evidence.

So I guess I'm -- for me, these are all, frankly, a bit subjective, but you want to be able to connect what you're saying as recommendations to what we know or don't know.

So that is totally reasonable, to say there's an explicit link, and the link is simply that there is no evidence. That's the one issue. I mean, there's lots of issues everybody has with all

Page 22

of these things, by the way.
But, yes, you need to be able to say what recommendations you're making and what evidence you're using or lack of evidence you're using to support that recommendation.
Q. And in the interests of transparency, you need to not only be able to say that, but you need to say it; am I correct?
MS. LEVI: Object as to form.
A. Yeah, I mean -- so these are, like -- these are things that they have said, "Gee, it's nice if we can do all of this," and you want to be able to say, in a guideline, did they do something. But I think there's still a lot of -- you need to sort of not be able to make such a stand, like, one dominant statement that there has to be a link between -- well, I guess -- I'm not a lawyer.
What I guess what I'm worrying about is that one doesn't need to be able to say there's supporting evidence. So the whole thing about guidelines and where AGREE sort of goes a little bit wrong is that the answer is that part of guidelines is also identifying big gaps and where we need more evidence.

Page 23

And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation?
And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So...
Q. You said in your answer, "I'm not a lawyer," and --
A. No, I'm not.
Q. -- just to be clear --
A. So none of us loves this stuff that's, like, so specific. But, yes.
Q. But just to be clear, this is also not a legal document.
A. Right.
Q. And I'm asking questions precisely to understand kind of the boundaries of how you as a practitioner understand the document.
A. Okay.
Q. And it's indeed how you understood it when you were embarked on the project we just looked at, where you attempted to be guided by the AGREE II criteria, correct?

Page 24

A. Yes. But we were, in our guideline, definitely dealing with a lot that had no evidence behind it.
So for us these are very -- you know, you're sort of doing your best to say, "Okay, here's the framework we're trying to work in and how do we work when there's not much evidence."
So what I don't like about Number 12, if you want to focus on that, is this concept of explicity and supporting evidence where, what if there is no explicit link, and what if there's no supporting evidence.
You still could meet the AGREE II criteria. You still could explain how you came to your recommendation.
Q. If you turn to Page Number 2 in the document, there's, towards the bottom, "Domain 6. Editorial Independence." And the first item there, Number 22, is a little differently phrased between AGREE and AGREE II.
The AGREE II statement from 2017 says, quote, "The views of the funding body have not influenced the content of the guideline," close quote.

Page 25

Do you consider that to be an important criteria for the reliability of a guideline?
A. Yeah.
Q. Why?
A. Well, I think there's -- the way I've always read this, at least, is -- and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay.
And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is -- I don't know, you were sort of -- and I think there has been some trying to understand.
But there is worry that there's groups that are funding guidelines that would like them to take a certain direction. And so it's just important to make sure that whoever is funding the guideline isn't actually influencing it, that they're kept totally out of the loop.
Q. Let me ask you to turn to Page Number 20.
Actually, let me back up for a moment here. I should show you the context of what we're in. If

Page 26

you back up to Page 6, you'll see a heading that says "User's Manual." And the next page says "User's Manual: Instructions for Using the AGREE II."

Now, whether or not in this form, do you believe that you have seen an official set of instructions for how to apply the AGREE II Instrument?

A. So -- this probably is the most I've ever really looked at it.

Q. But you've seen it before, you think?

A. I've followed a methodologist who probably was using it.

Q. Okay. You don't consider yourself is methodologist?

A. I'm not a methodologist.

Q. Can you describe -- when you distinguish yourself from a methodologist, what is the expertise of a methodologist that you relied on in the course of your own projects relating to developing guidelines?

A. So the methodologist guides the process, and they're making suggestions about what methodologies to be used.

Page 27

Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines?

A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of.

Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct?

A. Into, yes, the very specific words.

Q. And that's not you. You didn't go and consult the document step by step --

A. No.

Q. -- as you went?

A. No.

Q. You would talk to a methodologist?

A. Yes.

Q. Okay. Then all I can do is ask for your understanding as a result of having done that on the -- how did you pronounce that bunch of letters?

A. PEnQuIN.

Q. No, the organization --

Page 28

A. Oh, the NASPGHAN.

Q. NASPGHAN, there we go.

How many projects involved with developing clinical practice guidelines have you been personally involved in in your professional career?

A. A number. I don't know, actually.

Q. And in each one of those, there's been a methodologist involved you relied on?

A. No.

Q. How did you go about it in a case in which there was not a methodologist involved, since you don't consider yourself to be a methodologist, a methodology expert?

A. So I've been involved with guidelines since 2005, maybe was the first one that I got involved with, and there were no methodologists at that time. So, you know, it's a new concept, that you would bring somebody in who doesn't know the content but simply is an expert in the methodologies.

Q. Okay.

At any rate, if you turn to Page 20 now of the document, and indeed flip through whatever pages you like, and I think you will see that kind of item by item from the table we looked at earlier, there

Page 29

are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly?

A. Yes.

Q. And are you on numbered Page 20 now?

A. Yes.

Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence."

And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be -- is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7?

MS. LEVI: I'm going to just let you know, you can take the time that you need to --

THE WITNESS: Look at what's happening here.

MR. BROOKS: Absolutely.

MS. LEVI: -- look at this before you answer the question.

THE WITNESS: Yeah. I was sort of

Page 30

looking --
MS. LEVI: Flip through the document. Take whatever time you need to familiarize yourself.
THE WITNESS: I appreciate that.
MS. LEVI: Yeah. Of course.
A. Okay. So ask the question and let me see if I can understand what I'm looking at to answer it, maybe.
Q. You earlier described the kind of primary function of AGREE II as a tool to evaluate a set of guidelines after it's been created?
A. Yes.
Q. And you mentioned that your team on the NASPGHAN project had said, "Well, let's keep those criteria in view as we do it, rather than only afterwards," right?
A. Yeah. And actually, I will say -- it was on Page 0. It says it provides a methodological strategy for the development of guidelines. So that's the way we chose to use AGREE II.
Q. Perfect. And my question is, as we look at Page 20, or indeed a number of pages here, is it consistent with your understanding that this is designed for a user who is attempting to evaluate a

Page 31

set of guidelines to, on a point-by-point basis, assign a rating, a strength rating between 1 and 7, and there is discussion that tells you how to go about deciding that strength rating?
A. What I will say, looking at it, obviously again, and remembering working with it, is one needs to Likert scale -- so you're giving a rating -- and then they're attempting to at least give you how you want to think about that Likert scale; so, you know, what you should look at and how to rate it and, you know, what you're considering. And then honestly, in the end, you're going to use your best gut -- you know, your judgment on where you're going to rank them between 1 and 7.
Q. So I think I'm learning a fancy technical term for rating something between 1 and 7. Likert --
A. Likert scale.
Q. He gets credit for that, huh?
The beginning of the discussion under "User's Manual Description" on Page 20, and we're in Subheading 7, "Systematic methods were used to search for evidence," the text reads, "Details of the strategy used to search for evidence should be

Page 32

provided including search terms used, sources consulted, and dates of the literature covered."
Do you see that?
A. Yes.
Q. And is that something that your team did when you published your NASPGHAN guidelines?
A. Yes.
Q. And why did you consider that to be important information to disclose to the user community?
MS. LEVI: Object as to form.
A. Right. So I think one needs to make sure, when you develop a guideline, that you explain how you searched for evidence.
I will tell you, what stood out to me immediately in this sentence is I think there's supposed to be a comma after "provided." So these are just -- I mean, lots of people have lots of different ways of searching for evidence, so there's lots of ways you could explain what you did.
And if you're going to do A -- there's a lot of "mays" in the rest of this paragraph, but if you are going to do some sort of electronic searching, then, yes, you're going to use very

Page 33

specific search terms.
It's possible you don't have an electronic database of what you're looking for, so you'd still be able to explain that. The important thing is to explain what strategy you used to search for evidence.
Q. And have you made any effort to determine whether, in connection with the SOC-8 guidelines, WPATH disclosed search terms or information sufficient to replicate the searches done?
A. Have I made efforts? Can you explain what you mean by that. I read the website.
Q. Do you know whether WPATH, in connection with SOC-8, disclosed search terms or other information sufficient to replicate the searches they did for evidence?
A. So I read the website. I haven't, like -- and then I'm trying to remember it. But I have memory that they explained how they went looking for their evidence, and also they had moments when they knew there wasn't evidence. So they were making decisions along the way of what to do if there was nothing in the literature.
Q. Do you know whether WPATH, in connection

Page 34

with SOC-8, disclosed search terms used?
A. So I don't know.
Q. And do you know whether they disclosed enough information of any type to replicate searches that they did for relevant evidence?
A. My memory is that it was a transparent, rigorous process, where they explained how they searched for evidence. I don't remember looking or understanding if they had specified the search terms on the website, is the truth. I don't remember that. But they explained how they did systematic literature reviews, in my memory.
Q. The second sentence reads, "Sources may include electronic databases," and then it lists some examples, "databases of systematic reviews," it lists the example of the Cochrane Library and DARE, "handsearching journals," and it proceeds.
Then it says, in the final sentence, "The search strategy should be as comprehensive as possible and executed in a manner free from potential biases and sufficiently detailed to be replicated."
And, again, I want to ask you whether you know whether, in any context relating to SOC-8,

Page 35

WPATH disclosed how it conducted its searches with sufficient detail to be replicated.
A. My memory of the website is they explained that they did detail -- you know, they did a systematic literature search and that they explained how they came up with their evidence. But beyond that, I don't know. I didn't look.
Q. You would agree with me, would you not, that telling the world that you did a systematic search is a very different thing from describing with enough detail to be replicated?
A. Not per se. I think -- you want to explain how you did your search, and ideally somebody can go and do the search and feel that you found the same evidence, but I think -- you know, what is that? What is sufficiently detailed?
To me, again, there's a lot still that's very sort of, you know, subjective. And that is why I think, in the end, this description is giving us how to do this. But you're -- in the end, there's a Likert scaling, and you're going to use your best judgment on whether somebody did something in a sufficiently detailed way.
Q. Let me ask you to look at the next page,

Page 36

Page 21, and this, still under "Rigour of Development," is a new criteria that states, quote, "The criteria for selecting the evidence are clearly described," close quote.
And there the first sentence reads, quote, "Criteria for including/excluding evidence identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated."
Do you have any knowledge as to whether, in connection with any aspect of SOC-8, WPATH disclosed the criteria it used for including or excluding evidence?
A. We're not looking at the website, but my only memory is that it seemed like a very reasonable thing that they explained as to how they did their search, including the inclusion/exclusion criteria.
Q. Do you have any recollection that they provided any inclusion or exclusion criteria?
A. So I know, or my memory -- and, again, this is, for me, common in pediatrics and even common in what I did -- that they felt there weren't many randomized controlled trials. So they were not

Page 37

going to be limiting things to just randomized controlled trials.
And then I think this concept of excluding articles not written in English, that's pretty common for all of us to sort of struggle with, like, at what point do you want articles written in other languages, or do you just limit it to English-speaking publications.
MR. BROOKS: Let me ask the reporter to mark as Exhibit 3 a printout of a web page from the WPATH website that says -- that's entitled "methodology for the development of soc8."
(Document marked as Lightdale Exhibit 3 for identification)
Q. Obviously I'm showing you paper rather than the screen.
A. I appreciate that.
Q. Did you, in fact -- well, let me ask first, would you look through this and see whether this appears to be a printout of the WPATH methodology web page that you mentioned a moment ago.
A. Yes, in the sense that it looks really different. I think that on the web you see these sort of -- these pictures, like a tic-tac-toe box.

Q. You do. But let's focus on the text and see whether -- if you keep going, you'll get to text.
A. Okay. Yes.
Q. "Yes," this looks like what you recall looking at?
A. Yeah.
Q. And how long did you spend -- well, did you print this out and study it on paper?
A. No.
Q. You just looked at it on the screen?
A. Yes.
Q. And for about how long did you study that on the screen?
A. I mean, you had to open up each of those boxes and sort of look at things, but probably an hour maximum.
Q. Okay. Would you point me to anything in this WPATH web page methodology that either discloses or talks about disclosing criteria for inclusion or exclusion of evidence.
A. Okay. So let me take a minute to see.
Q. Take your time.
A. (Reviewing document) Yeah, no. So

basically what they are saying -- it's right here is where they're really talking about their systematic review.
Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10?
A. Yes.
Q. And 2.4.2?
A. 2.4 -- it's 2.4.1 and 2.4.2.
Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies?
A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where they're specifying the population, et cetera, PICO questions.
And I do not see in this piece of text that they talk inclusion/exclusion criteria. They say they conduct their systematic reviews.
Q. Did you, yourself, study any portion of the Standard of Care 8 itself, recommendations and

associated text, to evaluate any disclosures that may have been made in the guideline itself?
A. I didn't look at the SO -- I didn't look at the guideline.
Q. Okay.
If you turn in the AGREE II document, Exhibit 2, I think that was --
A. Yeah.
MS. LEVI: Take your time.
Q. -- to Page 22, at the beginning -- now we're under a new heading here, quote, "The strengths and limitations of the body of evidence are clearly described," close quote.
And the first sentence there under "User's Manual Description" reads, "Statements highlighting the strengths and limitations of the evidence should be provided." And then it continues, "This ought to include explicit descriptions - using informal or formal tools/methods - to assess and describe the risk of bias for individual studies and/or for specific outcomes and/or explicit commentary of the body of evidence aggregated across all studies."
Do you see that?
A. Yes.

Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study?
A. So all studies have some bias in them -- that's what you learn in the responsible conduct of research training -- and it is important to consider studies that way.
And in this case they're saying -- they're asking -- this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at.
Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer.
A. Well, I mean, "bias" is a big word, and it's not something I personally -- I mean, I just walk around with my own head -- where we all have unconscious ways of thinking about things. And then sometimes, especially in medicine, there can be very explicitly conscious bias where you really hope something works.

Page 42

So you have to be looking at a study to understand whether it was designed in a way to ideally account for the fact that there's bias.

And then when you write a guideline, you're going to be thinking about -- or you're trying to assess evidence, assess a study, you're trying to say, "Okay, how would I rate this bias and/or think about this bias?"

And, again, for AGREE, bringing it back to this, you would want to have a way that you went through your evidence and you said, every study, "Okay, this is what I found, but what was the risk of bias in the study?"

So there are usually worksheets you're working through as you look through every piece of evidence, or something like that, that lets you systematically say what the bias is.

Q. And in this context, bias isn't limited to situations in which -- isn't limited to the issue of humans who are involved wanting one result or another; it can also include an experimental design that just skews results, can it not?

A. Bias can, yeah, be a lot of different things.

Page 43

Q. It doesn't necessarily imply any conscious intent on the part of the people involved in the experiment?

A. Yes. Bias can be both, I mean, conscious and unconscious. It can happen accidentally, systematic bias, built in.

Q. You can have an experimental structure which results in false positives, and that would create a risk of bias?

A. Or false negatives.

Q. Or false negatives.

A. Absolutely.

Q. Okay. I just wanted to make sure we didn't misunderstand it as a layman might ordinarily understand "bias."

A. Okay.

Q. Do you know whether, in connection with any of the recommendations in SOC-8, WPATH disclosed or provided any description of risk of bias of studies that it relied on?

A. I didn't look at the guideline, so I can't comment on that.

Q. And nothing in the methodology web page that you looked at told you about that either, did

Page 44

it?

A. (Reviewing document) Well, I mean, what I can tell you is that they presented evidence tables, so I would need to understand what's in the evidence table. But presumably part of the evidence table is how strong was the evidence, and bias takes away from strength.

Q. So do you have an understanding of what an evidence table is?

A. I mean, in the abstract. Like, tables can look lots of different ways.

Q. But explain to me in the abstract what an evidence table is.

A. So, evidence tables -- and actually, I think somewhere I just read they've been commenting on this -- they can look lots of different ways. But it's a way of explaining what you looked at that you're saying is your evidence for what you're going to make a statement about.

Q. And did your NASPGHAN team publish, make available to the user community, evidence tables relating to those guidelines?

A. So we put a lot of appendices on. So we filled out a lot of different worksheets as we read

Page 45

every paper. I mean, everybody was assigned different things to read, and then you had to sort of start to build it up and put it more and more synthesized together.

So, yes, along the way there are different tables that give evidence for each recommendation.

Q. Things that, to your mind, fall within the general description of evidence tables?

A. Again, evidence tables are -- it's kind of a vague concept in the sense that there are so many different ways you can lay out what your evidence is. But, yes.

Q. And I'm not asking about a specific format.

A. Yeah.

Q. I think you've described the flexibility of that.

Do you have any knowledge -- why is it important, putting aside format, to publish, to make available to the user community evidence tables presenting the evidence that you -- that underlie your guidelines?

A. Well, I mean, I think it is important, when you put out -- again, this may be where we are now in 2024, but when you put out a recommendation on

Page 46

how to practice medicine, you want to be able to say that your recommendation is backed up by different -- you know, ideally different studies or at least different findings that would make up your recommendations. So...

Q. Is it also important to do that to enable other members of the medical, scientific community to evaluate whether they agree or disagree with your treatment of the evidence?

A. Yeah. I think that's part of the transparency piece of guidelines.

Q. And do you have any knowledge at all as to whether, in connection with SOC-8, WPATH published anything that could be described as evidence tables?

A. I don't know. I don't know.

Q. Turn with me, if you would, to Page 38. And this is under heading "Editorial Independence." This is the language we looked at earlier. There it says, Item 22, "The views of the funding body have not influenced the content of the guideline."

And it says, at the end of the first paragraph there, quote, "There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations,"

Page 47

close quote.

Do you see that?

A. Yes.

Q. Who funded your NASPGHAN guideline project?

A. It was mostly sweat equity, a lot of volunteer effort. But there was a little bit of funding from both societies.

Q. And in the case where there is external funding, do you consider it important -- an important aspect of transparency to disclose interests of the funding body?

A. So I think it would depend exactly what the external funding is. So -- you know, I'm just looking at this list, and some of these I would want to know are -- you know, are very appropriately disclosed, and some -- I don't know if it's as important. So... "Pharmaceutical companies" is the one that stands out in that list.

Q. And why is that?

A. I think a pharmaceutical company has a -- I'm going to use a word I shouldn't use -- vested interest, I think that's the right word, but they have money at stake depending on how a guideline goes.

Page 48

Q. A financial interest?

A. Yeah, sure. That's a better word.

Q. I think that term gets used in various of the documents.

Do you have a view as to whether it is, in fact, important, as it says here in this first paragraph, that, quote, "there should an explicit statement that the views or interests of the funding body have not influence the final recommendations"? And you commented earlier that that language had changed.

A. Yeah.

Q. So what's going on there?

A. It has changed. And I think that -- by the way, this is, again -- these are things you might fill out this and -- you know, every guideline has somebody -- usually, by the way, it's a group of people that are going to use this Likert scale and then come to consensus around the Likert scale. So there's, you know, even consensus building around, okay, where do we feel.

But I think that there has been, as guidelines have become more and more important, there has been more pharmaceutical money in the mix,

Page 49

and it has become important to make a statement, intriguingly not that you don't have a pharmaceutical company funding you -- this implies you could have a pharmaceutical company funding you, but you should explicitly state that that pharmaceutical company did not influence the final recommendations, which has been an odd thing the whole time. Like, looking at it, you're like, "Who would let a pharmaceutical company influence your final recommendations?" But anyway, I guess you need to be able to do that.

Q. You think such a thing has never happened?

A. They'd like to, but...

Q. Do you believe that the language was changed to require an explicit statement -- these aren't requirements -- to call for an explicit statement precisely to force the participants to focus on ensuring that there is no influence from the funding body?

A. Intriguingly, no, actually. I think what this was saying, and what AGREE II seems to have done, is allow for pharmaceutical companies to be involved in guideline development, or at least to fund them. As long as you write a statement and

Page 50

disclose that they're involved, it's saying, Okay, you can say that -- you know, that seems to be okay.

So it's almost allowing for this, as opposed to before -- or whatever. I think before, none of us would have thought that this could be happening, but... So we've moved into, "Well, just make a disclosure statement about it."

Q. Well, it's not just a disclosure -- only a disclosure statement, is it, Dr. Lightdale? It calls for an explicit statement that views and interests of the funding body have not influenced the final recommendation, correct?

A. It's calling for that. It's saying you should make that statement.

Q. And that goes beyond disclosure of who the funder is?

A. I mean, it's saying "the funding body." So this particular statement is the funding body, right, that they're asking for.

Q. Let me ask you to turn to Page 41, which is headed "Overall Guideline Assessment."

A. Yes.

Q. And this simply asks the rater, having completed everything else, to rate the overall

Page 51

quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale.

But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No."

Do you see that?

A. Yes.

Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify?

A. I think so. I mean --

Q. What is it?

A. -- it would mean that the rater does not think the guideline should be -- it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor.

MR. BROOKS: All right. Let me ask the reporter to mark as Exhibit 4 the Expert Rebuttal Declaration of Dr. Jenifer Lightdale.

(Document marked as Lightdale Exhibit 4 for identification)

Q. And here let me -- Dr. Lightdale, if you would just take a look at this and confirm that this

Page 52

is a copy of the report you submitted in this case.

A. Yeah.

Q. If you would turn to Paragraph 26.

Let me ask you a quick question. Have you served as an expert witness before this case?

A. On a couple of occasions. Not a case like this, but, yes.

Q. All right. And did anybody assist you in preparing your actual written report?

A. No.

Q. Let me take you to Paragraph 26, and there you explain what GRADE is, all caps, G-R-A-D-E. We'll talk about that a certain amount. And you state that GRADE "is currently the most commonly used system for classifying evidence and the strength of recommendations."

Do you see that?

A. Yes.

Q. And what is the basis for your assertion in your expert report that GRADE is the most commonly used system for classifying evidence?

A. Just gut instinct, like what you're hearing everyone talking about.

Q. Is there any close competition, or is GRADE

Page 53

really by far the leading methodology used to rate the strength of evidence today?

A. I would say it's the main way that people are using -- or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that.

Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper.

And in this paper we looked at your reference to AGREE there, but in the course of this work -- I don't mean to make a memory test -- if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column.

So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality of the evidence you found?

A. Yes. That's how we chose to rate evidence.

Q. And you, in fact, used the GRADE rating system at two stages; am I correct? That is, first you used it -- I'm looking about an inch and a half from the bottom of the first column on 32 -- first used it "to assess the quality of evidence ('very

Page 54

low,' 'low,' "moderate," or 'high),'" and then a few lines down it says, "The GRADE approach was then used to determine the strength of recommendations as 'strong' [or] 'conditional,'" correct?
A. Yes.
Q. So GRADE provides means of rating both the strength of evidence and the strength of recommendations, right?
A. Yes. You can use it that way, yes.
Q. And your team did use it that way?
A. Right.
MR. BROOKS: Okay. Let me ask the reporter to mark as Exhibit 5 excerpts -- an excerpt from the WPATH SOC-8, which is appendices, including Appendix 8 titled "Methodology."
(Document marked as Lightdale Exhibit 5 for identification)
Q. Dr. Lightdale, I've got the cover page -- SOC-8 itself is a very long document, and I have not put the whole thing in front of you. You will see the cover page, the table of contents, and then, beginning at Page S247, "Appendix A, Methodology."
A. Okay.
Q. And my first question for you is -- let me

Page 55

ask you to flip through that Appendix A, which is perhaps six pages long, and ask whether you think you have ever seen this document before.
A. Okay. I'll just flip through it. I have not looked at it before.
Q. Okay.
A. I will need to look at it if we're going to start talking about it.
MS. LEVI: Take the time you need to look at it.
THE WITNESS: Okay. Okay.
Q. Let me ask you --
A. I don't want to start to speed read.
Q. No, that would be ill-advised.
But first, let me ask you this: Did you know that SOC-8 had a methodology appendix as part of the published standard of care?
A. No.
Q. When you were asked to prepare your report, somebody directed you to the methodology web page but not to the methodology appendix?
A. I mean, I was in the web page. I'm, like, going through different --
MS. LEVI: And I'm just going to -- I want

Page 56

to make one objection, and clear to you, that in answering the questions, you are instructed not to disclose any conversations you've had with counsel.
THE WITNESS: Okay. Okay.
MS. LEVI: His questions aren't directed towards that.
MR. BROOKS: That is correct. I feel strongly on that point.
Q. Well, since you didn't know it existed, I was going to ask why did you choose simply to rely on the web page rather than the appendix that is more detailed, but the answer is, you didn't know the appendix existed?
A. Well, I don't remember knowing about that. But I will tell you, I mostly stuck with what was described -- I was asked, I got a phone call and was asked, could I look at this and make comments, and I made some comments based on the web page. So...
Q. Okay. Let me call your attention to Page 250 in the methodology appendix that's Exhibit 5, and there's a short paragraph headed "Grading of the evidence."
A. Okay.
Q. And that states, quote, "The Evidence

Page 57

Review Team assigned evidence grades using the GRADE methodology. The strength of the evidence was obtained using predefined critical outcomes for each question and by assessing the limitations to individual study qualities/risk of bias, consistency, directness, precision, and reporting bias."
Do you see that?
A. Yes.
Q. Do you have any knowledge as to whether, in fact, anybody within the SOC-8 team ever assigned evidence grades to any evidence using the GRADE methodology?
A. No. All I have is their instructions.
Q. If the team told the world, in the published appendix, that they assigned evidence grades using the GRADE methodology, and in fact they did not do so, you, as a person with expertise in developing clinical practice guidelines, would consider that to be quite problematical, would you not?
MS. LEVI: Object as to form.
A. I'm also feeling like -- can you repeat the question, because I'm trying to focus on what you're

Page 58

asking.
Q. If the SOC development team told the world, in their methodology appendix, that they assigned evidence grades using the GRADE methodology and in fact it did not do so, that would cause you serious concern as somebody with experience in developing and using clinical practice guidelines, would it not?
A. So as someone who has experience, I can tell you that the GRADE methodology can be applied in different ways. So I would have to understand more why someone is telling me that it wasn't done, because there are so many ways to use it. So...
Q. My question is a simple and a hypothetical one.
A. Okay.
Q. If they told the world, "We assigned evidence grades using the GRADE methodology," and they simply did not do so, that would cause you serious concern, would it not?
MS. LEVI: Object as to form.
A. I would be mystified why they would do that.
Q. You wouldn't go so far as saying it would

Page 59

concern you?
A. Honestly, I'd be more concerned with somebody trying to say that it didn't happen and to say, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then put it into use in the sense of -- I mean, there's -- whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways.
So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology -- as we went through our development process, we had to make decisions about how we were going to use GRADE methodology.
So for me it would be someone telling me, "Oh, it didn't happen." I'd say, "Well, how do you know that? You know, why are you saying that?" That would be the bigger concern, to be honest.
Q. The GRADE system for rating evidence has a specific set of four levels of strength, correct, as described in your NASPGHAN document; that is, very low, low, moderate or high?
A. That is how we did it, for sure.
Q. And, indeed, definitions of those terms are

Page 60

specifically set out in the GRADE system, correct?
A. Not per se. There's actually a fair amount of ways that you can make decisions yourself about how you are going to grade evidence. So -- and then the strength of recommendations.
And for instance -- and I'm not, frankly, looking at what you've given me. But, you know, how are you going to decide something is of high quality? How many -- how are you going to decide some of this stuff?
And so even the process of putting together a guideline is a certain amount of consensus about how you're going to use GRADE methodology. So I don't think it's black and white. It's a process you go through.
Q. Is it your testimony, Dr. Lightdale, that the GRADE system does not provide black-and-white definitions, textual definitions of very low, low, medium and high quality evidence?
A. It gives you that way of ranking your evidence. But in terms of what does it mean to be high quality, that can also be, like, decided along the way of what we're going to decide is high quality evidence. So that is not a highly -- that's

Page 61

not a firmly defined thing, high quality evidence.
Q. As you sit here today, you don't recall the precisely defined meaning of high quality evidence from GRADE?
A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence.
So the classic is randomized controlled trials can be high quality evidence, but so can very well defined -- or, you know, designed observational trials.
So you can't just say, just because something is an observational trial, that it's not the same evidence -- or not the same quality. You actually need to be assessing every study, no matter what the design is.
So, again, high quality is a process to decide something is of high quality when -- okay. I'll try to stop talking.
There's a lot of ambiguity here.
Q. Was WPATH's use of the widely accepted GRADE system for classifying the strength of evidence and the strength of recommendations an important part of the basis for your conclusion in

Page 62

your expert report that, and I quote, "WPATH's method for developing SOC-8 is exemplary," close quote?

A. I made that statement because I was so impressed by how they had spelled out their entire process on the web page for developing their guideline and had really shown it to be very carefully a priori thought about, it was very rigorous, it seemed to me to be very transparent in what they had done, how they had come up with their groups, how they'd organized themselves. They gave a lot of information there that, honestly, most societies aren't doing at this point.

So it was very impressive how they had taken a lot of steps to spell out what they had done.

Q. Was their use of the widely accepted GRADE system to rate evidence and the strength of recommendations an important part of the basis for your conclusion that their method for developing SOC-8 was exemplary?

A. No. I would say it was more that they said what method that they used.

So, you know, I think -- I mean, again,

Page 63

GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is.

But I think you could -- I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process.

MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be --

MR. BROOKS: Let me -- I'll wrap up this series of questions shortly.

MS. LEVI: Okay.

MR. BROOKS: If you're all right, we'll go for a few more minutes.

Q. In the second column on Page 250, S250, is a section "Grading criteria for statements." Do you see that?

A. Yes.

Q. And there, in the second sentence, it says, quote, "This is a transparent framework for

Page 64

developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations," and it cites Guyatt, et al., close quote.

Do you see that?

A. Yes.

Q. Does the name "Guyatt" mean anything to you?

A. So for me it is a reference that one often uses when you are explaining that you used GRADE. So, you know, it's a person.

Q. Do you know who Professor Guyatt is?

A. Not in any meaningful way, no.

Q. Do you know anything about his reputation in the field of evidence-based medicine?

A. He is the first author on this sort of important text that you use to say you're using GRADE.

Q. You've never heard him speak at a conference?

A. No. No.

Q. Okay. In your report you mention that some criticisms have been made of the GRADE system of evaluating the strength of evidentiary support, but

Page 65

you, yourself, have recently used GRADE --

A. (Nods head)

Q. -- and I think you've -- you have to...

A. Oh, yes. Sorry.

Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently.

A. (Nods head)

Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct?

A. Yes.

Q. What was your point in mentioning that GRADE has been criticized?

A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right?

So -- and that, by the way, is everything. That's the evidence we're using to make the guidelines or lack of evidence. That's how we create groups that are going to make the guidelines. And then there's actually how you're going to put the guideline together and the methodology you're

Page 66

going to use.
And in there is GRADE has emerged as a methodology we're all coalesced around, but you know that it is not perfect. And I'll say to my own, there are many different ways you can use it. And so part of process is even deciding how you're going to use it, and, you know, there are still a lot of judgment calls to it.
So in pursuit of perfection continues, and therefore, criticism is welcome to keep making it better.
Q. All right. Well, you've made some criticism of GRADE in your expert report. Let me ask you this.
A. Yes.
Q. Have you ever published -- have you ever, in any publication, criticized GRADE in any way?
A. No.
MR. BROOKS: All right. Let's take a break.
MS. LEVI: Okay.
(Recess)
MR. BROOKS: Let me ask the reporter to mark as Exhibit 6 an article from 2011 entitled

Page 67

"GRADE guidelines: 3. Rating the quality of evidence."
(Document marked as Lightdale Exhibit 6 for identification)
BY MR. BROOKS:
Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series -- a numbered series of papers published that detail the GRADE system?
A. I'm familiar.
Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last.
Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper?
A. Yes.
Q. What is that?
A. So, generally speaking, the last author is your senior person, who then is usually looking at the first person -- those two people are usually the people who are writing the paper together.
Q. Okay. The first person probably did the most work, and the last person is the most senior --
A. Senior, yes.
Q. -- responsible person.

Page 68

So Dr. Guyatt has got some subordinates, but he is the senior person on this project?
A. (Nods head)
Q. Do you think that you have ever before today seen -- and there are, I think, at least 15 in this numbered sequence. I'm not going to put them all in front of you, I promise.
Do you think you have seen any of these numbered papers setting out the GRADE system?
A. I don't know that I've ever seen the papers specifically before.
Q. Okay. I want to call your attention to Page 404, Table 2, which provides statements of the meaning of the four levels of evidence. And I'll -- there are many places I could have gone to show you these same definitions. This is just one.
And there's two columns -- there's three columns. One is "Quality level," "High," "Moderate," "Low," "Very low." The second column says "Current definition." And, again, this paper is as of 2011. And the final column reads "Previous definition."
Let me ask you to look at the column that says "Current definition" and tell me whether those

Page 69

are indeed the definitions of -- or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with.
A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit.
Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect."
Do you see that language?
A. Yes.
Q. And do you have an understanding of what that means, what it means if you assign that rating to the results of a study?
A. So, yes.
Q. What is that understanding?
A. So I think this -- a lot of this is subjective ratings of evidence. And here, when you -- when the group decides something's of low confidence, or frankly if an individual is doing their grading of evidence as part of the process,

Page 70

you would say that your confidence in what's been found, or the effect estimate, is not great, and that the true effect might be different from what is being found, or not found, as the case may be.

Q. Just to pause for a moment. Am I correct that it is considered good practice, if you're rating a body of evidence, to have more than one rater independently evaluate each study?

A. We have, yeah.

Q. And then did you have a process for resolution if they disagreed?

A. Yes.

Q. Was that documented in any way in what you disclosed to the public in connection with your NASPGHAN guidelines?

A. I don't think it shows up in the final paper exactly. It's more -- well, actually, there are a couple of times that we couldn't come to consensus, and we make that clear, that we have certain things that we couldn't come to consensus on.

And by the time you get to that point, you've gone through a lot of process here. This is around grading the various pieces of evidence that

Page 71

are going into your recommendation.

But, yes, sometimes there was not enough to even achieve consensus.

Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect."

Do you have an understanding of what is meant by that definition of a very low rating?

A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far.

Q. What does it mean to say that the true effect is different from the estimate of effect? I think, to a layman, that might be a bit cryptic. What does that mean?

A. So what it would mean -- again, and I'm sort of staying away from statistics, which affect estimate to some extent. It could be interpreted statistically, but it also can be just interpreted

Page 72

in terms of what we know and what's been found and what's estimated to have been found, because even statistics are just estimates.

So I think when you say the true effect is likely to be incredibly different from what is known, it's usually in a situation where we just don't have much of an estimate of effect or even any estimate of effect; and therefore you don't really know, and you actually -- not only don't you know, but you don't have any confidence in what is being -- is out there.

Q. So if you assigned a rating of very low to an individual published study in which a certain treatment is administered and a certain outcome is reported, am I correct that what you are saying with that "very low" designation is, "The design of the study is such that I have no confidence that, if it was repeated on a different patient, you would get the same outcome"?

MS. LEVI: Object as to form.

A. Yeah, well -- I'm actually not --

THE WITNESS: Can I answer? Or is that --

MS. LEVI: Yes.

A. I'm actually not sure that it would be

Page 73

about design of the study. It's just -- the bottom line there is, you have a very low confidence in the -- well, this is about GRADE, but you have very low confidence in the known evidence that's out there, and that if there was a different study or perhaps -- perhaps a different design, but it also could be that -- what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people.

Q. Okay. Fair enough.

Let me take you to the first page of this paper.

A. Okay.

Q. Exhibit 6.

A. Yes.

Q. "GRADE guidelines: No. 3." And on the first page in the second column is a Heading Number 2, "What we do not mean by quality of evidence," and then Heading 3 that says, "Opinion is not evidence."

Now, you testified earlier that -- I forget exactly what year you said, but you may have said

Page 74

about 2005 -- this evidence-based medicine wasn't a thing yet?
A. Well, 1995.
Q. 1995, thank you.
A. When I graduated from medical school, it was just coming around.
Q. I see the heading here that says, "Opinion is not evidence." And do you have an understanding of what that means, what's being said in the context of evidence-based medicine?
A. Let me take a look at what they wrote here in this paragraph.
Q. Please.
A. (Reviewing document)
MS. LEVI: Take your time to review the whole article if you need to as well.
Q. And, look, if the answer is, "I don't have an opinion," that's fine. I just...
A. (Reviewing document)
Q. Let me ask a better question.
A. Yeah, thanks.
Q. Let me withdraw that question, because I don't want to just have you sit here and interpret what they wrote.

Page 75

A. Great.
Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence?
MS. LEVI: Object as to form.
A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process.
And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. You know, there is constantly a give-and-take on where is there evidence, what does that evidence mean, how does it apply to whatever you're trying to look at it for, and then where is there more experience of it, experience driving opinion. So...
Q. Well, so let me see if I understand what you're saying. Sometimes expert opinion is all you have to go on. Is that part of what you're telling me?

Page 76

A. No. I think they wrote a lot of paragraphs here, because it is tricky in medicine to feel like things are black and white. So, you know, they're just not that specific. You just can't be.
And so they're taking a lot of time here -- again, I'd have to get into it more -- to think about something I think all of us in guidelines think about, which is, okay, what do we -- how do we take evidence, synthesize it, but also make sure that we feel like we can have opinions on the body of the evidence we're looking at and can make a recommendation.
I mean, that is the consensus process around guidelines and the guideline development process in a nutshell. It's we have got evidence, but then we have to go beyond evidence, because evidence itself is not good enough, basically.
Q. For purposes of guideline -- as the terms are understood today in guideline development, do you consider expert opinion itself to be scientific evidence?
MS. LEVI: Object as to form.

Page 77

A. So expert opinion, again, is -- I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion?
So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like -- I mean, there's just basically -- it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance.
Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of -- in your own field, I assume there are some people who everybody would acknowledge are experts, true?
A. Experts are people who have emerged as giving statements and leading a field, but every expert does come with their own ways that they do something.
And so, yes, you can see somebody as an expert. You also want to understand how they -- how they do it. So you sort of have to look beyond just are they an expert and say, "Well, why are they an expert, and is that what I need at that moment?"

Page 78

Q. We talked earlier about evidence tables and rating the strength of evidence. For purposes of developing clinical practice guidelines, do you consider expert opinion to be scientific evidence?
A. No. I think it's important. So expert opinion becomes as important as whatever's been published as evidence.
Q. Okay. Let me take you back --
THE WITNESS: I have a bad question. Am I allowed to have a Coca-Cola?
MR. BROOKS: Absolutely.
THE WITNESS: Get some sugar.
MS. LEVI: Just to be clear, at any time if you need a break, it's fair to ask for it.
MR. BROOKS: Exactly.
THE WITNESS: I left the coffee in the other room, and I think I need some sugar.
MS. LEVI: If you want me to get your coffee --
THE WITNESS: No, no, no. It was quite cold.
MS. LEVI: Nobody wants you to be uncomfortable.

Page 79

BY MR. BROOKS:
Q. If you would find Exhibit 1 again, NASPGHAN guideline -- I love that term.
A. Thank you. We've thought about a name change, but it's hopeless at this point.
Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing.
If you -- this paper, in fact, includes recommendations and suggestions -- this paper contains the guidelines that your team developed; am I right?
A. Yes.
Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about.
A. Okay.
Q. And this is -- Standard 36 is a conditional recommendation that, quote, "Endoscopic biopsies should be obtained as appropriate for the procedural indication, consistent with current evidence-based guidelines, when available."

Page 80

Am I correct that a conditional recommendation, in some guidelines, the term that's used for that is a "suggestion" or a "weak recommendation"?
A. Yeah --
MS. LEVI: Object as to form.
A. We had a very specific concept, which is "conditional recommendation" was defined as suggesting that implementation might vary. So it was recommended, but we knew that it might or might not be something people would choose to implement.
Q. Did it also, whether it was a conditional or unconditional recommendation, relate to any extent to the strength of the evidence that you had to support that recommendation?
A. So they were two different things that we were, you know, grading. So we were grading the quality of the evidence, and then we were also making a recommendation. And very often our conditional recommendations were where there was low quality evidence.
Q. And this is an example where you've expressly said up front that there was low quality evidence, right?

Page 81

A. Yes. This one had low quality evidence.
Q. And you also disclosed the vote in your consensus process?
A. Yes.
Q. Which was a Delphi process?
A. We used a Delphi process to come to consensus to vote on recommendations themselves.
Q. Is a Delphi process a fairly well defined thing in the art?
A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together.
But Delphi is well described, and it's an iterative, good process for coming to consensus. So...
Q. Is it a process -- is anonymity in the voting an inherent part of the Delphi process?
A. Yes.
Q. Why is that?
A. I think anonymity is a way of trying to mitigate bias, to come back to that word. So...
Q. Why is it important that the voting be

anonymous?
A. I think that the Delphi process is designed to let each individual stand, you know, in their own convictions and their own -- you know, to basically vote on their own decisions on how they want to do things.
And, yeah, it's just important, because it doesn't let necessarily one person sway a process, like what would happen in an open room. So...
Q. You might have somebody who is highly respected that more junior participants are reluctant to disagree with?
A. Sure. That could happen.
Q. You might have peer pressure of some sort, that somebody is reluctant to be the odd man out?
A. Yeah.
Q. Has every Delphi process that you've ever participated in been anonymous in its voting?
A. Yes.
Q. Why did you disclose the breakout of the vote?
A. We made a decision early on, before we did any of it -- again, working with methodologists and trying to decide how we were proceeding -- with what

we were going to do. So that was all decided a priori.
Q. If you back up to Page 36, Standard 32.
A. Yes.
Q. This standard says, "Pediatric endoscopic procedures should be performed efficiently, within a reasonable procedure time."
I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us?
A. Yeah.
Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct?
A. Yes.
Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; am I right in understanding this correctly?
A. Yes.
Q. Now, the recommendation that you perform these procedures efficiently within a reasonable time off the cuff seems, to use a technical term, a no-brainer.
Why was that recommendation only

conditional?
A. Well, I think there's a debate about frankly what is that. So pediatric endoscopy is a field where we take longer with colonoscopies for lots of different reasons, and I don't think we have tended to be focused on time the way that adult colonoscopists have.
And so there's actually a lot of people who are reticent. I'll tell you, I personally voted "strongly agree" there. I agree with you, for me this was a no-brainer. But there are a lot of people who are quite reticent to have there be some sort of regulation or, in this case, a standard, even, to say, you know, that time matters.
So that's still a foreign concept in pediatric GI. And it turned out we didn't have much evidence to say that it needs to happen in an efficient way.
Q. So in the evidence was low quality -- even if it seemed common sense, if the evidence is low quality, you would generally give only a conditional recommendation?
MS. LEVI: Object as to form.
A. Yeah, no, there are really two different

things. And so you sort of got to this, and then it was like, "All right, are we ready to vote on this recommendation?"
So, again, the conditional recommendation is saying that we're going to recommend it, but we appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective.
So then the voting, you're just seeing that it really -- and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level.
Q. Let me just put a caution out on the table. We do this all the time in ordinary speech. You began that answer, "Yeah, no."
A. Oh.
Q. And in a deposition, that doesn't work terribly well.
A. I didn't hear it. I didn't hear it. Okay.
Q. You know what I mean.

A. Yeah.
Q. It's just sort of a thing. So let me -- I'll just ask you a new question. It doesn't really matter. I'll just caution you.
A. Okay.
Q. Am I correct that, most commonly, if all you have is weak evidence for a recommendation, you would expect that recommendation to be a conditional or a weak -- a conditional recommendation or a suggestion?
MS. LEVI: Object as to form.
A. I mean, I think we -- we would say it's hard to make -- like, to have strong evidence and then have a conditional recommendation. And I think it's probably -- I mean, again, the low quality evidence is not going to make it possible to have a strong recommendation, usually.
Q. I can't promise we won't come back to that again. I just love it so much.
MR. BROOKS: Let me ask the reporter to mark as Exhibit 7 a paper from 2018, the lead author Dayna Early, a number of authors including Dr. Lightdale, entitled "Guidelines for sedation and anesthesia in GI endoscopy."

(Document marked as Lightdale Exhibit 7 for identification)
Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record.
A. Yes.
Q. What is this?
A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy.
Q. And "second author" implies that you -- there's a lot of names there.
A. Yes.
Q. "Second author" implies that you were substantially involved, more than many of those authors?
A. I was substantially involved.
Q. All right. And this is a different set of guidelines being created by a different team; am I correct?
A. Yes.
Q. Specifically for sedation and anesthesia,

not for the procedure itself?
A. Right.
Q. And, again, in this set of guidelines, your team used GRADE to rate the strength of the supporting evidence; am I right?
Not a memory test. I think it says so at the bottom of the first column on the first page.
A. I don't actually remember that we used GRADE.
Q. Well, again, I'm not testing your -- first page, first column, at the bottom of the --
MS. LEVI: You can take your time to read --
THE WITNESS: Yeah, let me --
MS. LEVI: -- and review your own article. That's okay.
THE WITNESS: Yeah, no, this is part of the evolution.
A. (Reviewing document) We used -- yeah. We used GRADE criteria at the very end to talk about the recommendations, but we didn't use GRADE methodology. This is -- this was the state of the art from, like, I don't know, 2010 to -- again, this came out in 2018. We were probably working on this

one in 2016, you know.
So we were using GRADE criteria -- actually, yes, published -- August 2017 is when we started looking at things.
But we didn't actually use the GRADE process.
Q. Well, let me ask this: The last line of the first column -- I was going to say "abstract," but it's not exactly an abstract, is it?
A. Yeah.
Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)."
And if we turn to Table 1, that is headed "System for rating the quality of evidence for guidelines." It's footnoted, "Adapted from Guyatt et al." And it has definitions which I -- we could take the time -- it matches the list of previous definitions in the table that we looked at earlier.
MS. LEVI: I'm going to ask, if you're going to respond to that question, that you make sure --

Page 90

MR. BROOKS: That's a representation.
MS. LEVI: -- that you are familiar --
Q. We can go back to my favorite document, which is to say Exhibit 1 -- no, it's not. Lightdale Exhibit 6 contains, on Page 404, the definitions.
MS. LEVI: Take the time you need to respond accurately to the question that may be asked.
Q. And my only point -- and there is no question at the moment -- my only point is that the list of definitions contained in your paper from 2018 seems to correspond to the column labeled "Previous definition" on Page 404 of Lightdale Exhibit 6.
And if you'd like to check that, that's fine.
A. Yes. It does.
Q. All right. And in the right-hand column in your 2018 paper is -- it says "Symbol," and it shows little circles with crosses.
Are those symbols widely used and recognized in connection with GRADE ratings?
A. Not necessarily. So without a doubt --

Page 91

it's funny, I have strong memories of this paper.
We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE -- again, everything has been an evolution, right?
Q. Right.
A. But this previous definition, we looked at that as we looked at our recommendations.
In other words, we came up with the recommendations and then we said, "Okay, how do we feel?"
And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor.
Q. Would you spell that for the reporter, PEnQuIN.
A. Sure. P-E-n-Q-u-I-N, which is the Pediatric Endoscopic Quality Improvement Network.
Q. Otherwise we're going get a transcript that has "penguins" all over it.
Let me ask this, because the guidelines

Page 92

related to sedation and anesthesia, they're not antique. 2018 is not that many years ago.
A. Correct.
Q. Why did your team not use a GRADE system for rating the evidence in the course of developing those guidelines?
A. So in 2017 -- again, my memory is probably in 2016 I got assigned this with Dayna in the Standards of Practice Committee that I was sitting on. And we basically -- we were just, as a society and as a group, and I would argue across most of medicine, people were really not yet ready to put in the tremendous effort it takes to do the GRADE process.
And so it's being discussed by experts out there and mentioned, and people are hearing the term, but what it actually means to do it is a lot of work. And that is not where we were at ASGE in, you know, 2016, 2017, as we were doing this thing, and it ultimately comes out in 2018.
MR. BROOKS: Okay. Let me ask the reporter to mark as Exhibit 8 one of the GRADE Series papers, No. 14, quote, "Going from evidence to recommendations: the significance and presentation

Page 93

of recommendations."
(Document marked as Lightdale Exhibit 8 for identification)
Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today?
A. No.
Q. Then I will ask you -- I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors.
So let me ask you to turn to Page 720 and -- actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark.
A. (Reviewing document) Okay.
Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the balance between desirable and undesirable consequences, they make a strong recommendation for.. or against... an intervention."
Do you see that?
A. Yes.
Q. And is that description of when a strong recommendation is appropriate consistent with how

Page 94

you have gone about deciding what merits or does not merit a strong recommendation?
A. I mean, yes and no.
Q. Okay.
A. So I think -- I have not sat in a panel and thought about this, you know, desirable, undesirable. We haven't sat there and weighed that kind of stuff.
But I would say, instinctively and inherently, to make a strong recommendation, you have brought into play discussions around desirable and undesirable consequences.
So people are thinking about that, and that could be either desirable health outcomes, or I think there's a lot of, I would call it, risk/benefit weighing that's going on with recommendations and what are the risks to making a strong recommendation for or a strong recommendation against something, what's the risk of that.
So strong recommendations are to be done very carefully.
Q. Well, the next sentence reads, quote, "If the panel has less confidence of the balance between desirable and undesirable consequences, they offer a

Page 95

weak recommendation."
Do you see that?
A. Yes.
Q. And is that relating to what you just explained to me?
A. Yeah. I think, again, in practice that kind of happens.
Q. So you need to be fairly confident that you understand -- let me start again.
You need to have a fairly confident evaluation of the upside of the treatment in question and also a fairly confident understanding of the risks or downside before you can offer a strong recommendation; am I correct?
MS. LEVI: Object as to form.
A. I guess I'm not sure if you're restating what I tried to state.
But I think a panel ultimately is -- everybody in that panel is, in their head, weighing what's good about making that recommendation and what could be a downside or undesirable or a risk of making a recommendation, or not making a recommendation.
I think a lot of this GRADE stuff is really

Page 96

pushing us. In fact, the abstract that you asked me to read says this. Don't shy away from not (sic) making a recommendation. It's important to make recommendations, because if you don't make a recommendation, you still leave people in the dark.
So it is a grappling process to try to figure out, okay, how do we make the recommendation.
Q. In that process, do you, as a physician -- well, let's take it in a clinical process system first.
Do you, as a physician, deciding on treatment for a patient, have an obligation to consider both long- and short-term consequences of administering the treatment or withholding the treatment?
MS. LEVI: Object as to form.
A. I would say not always, is the truth.
Q. In what context, if any, would you have no obligation to consider the long-term consequences?
A. When there's life or death on the line.
Q. Okay. And have you yourself faced those situations?
A. Yeah.
Q. And what degree of threat or imminence of

Page 97

death, to your understanding, makes it appropriate for you as a physician to put aside considerations of long-term impacts?
A. So I'm in pediatric GI, so we certainly encounter situations where, if we do not act within the next 15 minutes, somebody will die, and you actually do need to do something.
So, you know, not -- at that moment, I'm not worrying about the long term. I'm worrying about what needs to be solved at that moment to get the patient out of the situation.
Q. Absent an imminent threat of death, do you believe that you, as a physician, have an obligation to consider both long-term and short-term consequences of a potential treatment as you make decisions for or with a patient?
A. I'm in pediatrics, so long-term discussions of things is really tricky. You know, what are we talking? Five years out? Ten years out? Fifty years out? You know, that's -- no, I think we can't always be fully sure of the long-term stuff, because long term can be a very long time in pediatrics.
Q. It certainly can.
Do some of the types of treatments that

Page 98

you, as a doctor, participate in deciding have potential lifelong downside risks?
A. Sure.
Q. Give me an example.
A. We use biologics to treat inflammatory bowel disease, and they can have cancer risks down the line.
Q. So is that a context in which you do or you don't consider the long-term risk as you talk with parents?
A. I put it out there that there are potential long-term risks. But then I weigh it against other long-term risks, including not treating the disease with the biologics, which still holds a cancer risk. And there's almost no ways to really weigh these things. But people try to imagine long term, and, you know, I do my best to help them think about it. I think about it, et cetera.
Q. Is there other any other example that comes to mind of decisions you participate in that have potential lifelong implications?
A. Sure. I'm going to have to think now. That one came quickly.
Q. Go for it. Think.

Page 99

A. Yes. I'll give you one.
So in the diagnosis of celiac disease, there's a movement not to do endoscopy and get the biopsies that we read about in our standards, because that incurs risk to do that, especially in a young child.
So there can be a discussion of, do we really need to do the endoscopy? And the answer is, well, if you -- this is my thinking; I'm not an ethicist, but I explain that I think there is an ethical question on the line -- which is, right now, while the disease is not yet treated, if I do the endoscopy, we will have evidence of the disease. And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say, you know, "I'm not sure I ever had celiac disease. Maybe I don't need to be doing what I'm doing," that is a long-term potential complication that could come up.
So I say, "We better do the endoscopy, even though it has risks right now, because in 20 years, I want to give you what you need to assure your child that you did the right things to make the diagnosis."

Page 100

Q. Okay.
721, Column 2.
A. Okay.
Q. At the bottom is a section headed "Meaning of recommendations in GRADE." We've talked earlier about evaluating the strength of evidence, and now we're talking about the GRADE labels for recommendations.
And the first sentence in that section reads, "Using the GRADE approach, guideline authors make a strong recommendation when they believe that all or almost all informed people would make the recommendation choice for or against an intervention."
Let me ask whether that understanding of a strong recommendation is consistent with how you and your colleagues have worked, for instance, in creating the NASPGHAN guideline.
A. I don't know that we have used that exact framework for talking about when to use a "strong recommendation." So I hadn't read this before, and I don't remember that that was what we said.
MR. BROOKS: Okay. Let me ask the reporter to mark as Exhibit 9 GRADE Guidelines Paper Number

Page 101

15, "Going from evidence to recommendation - determinants of a recommendation's direction and strength."
(Document marked as Lightdale Exhibit 9 for identification)
Q. And, Dr. Lightdale, I assume, but correct me if I'm wrong, you have not seen this particular paper before today?
A. I have not. Shall I read the abstract?
Q. I'm going to take you -- you certainly may read the abstract, or you can listen to my question and then decide whether you want to read the abstract.
A. Okay. Go ahead.
Q. If you turn to Page 731, there is, on the first column, a heading "Confidence in estimates of effect (quality of evidence)." Do you see that?
A. Yes.
Q. And if you go down, the third paragraph below there begins, "For instance." Do you see that?
A. Uh-huh.
Q. Let me read that short paragraph into the record.

Page 102

"For instance, the GRADE approach provides insight into how guideline panels should have handled the decision regarding hormone replacement therapy (HRT) in postmenopausal women in the 1990s when observational studies suggested a substantial reduction in cardiovascular risk (which randomized trials subsequently proved false, at least in women appreciably past menopause), and equally low evidence quality suggested an increase in the risk of breast cancer (which proved true)," close quote.

Really my opening question is, do you have some familiarity with the narrative in the medical field of a period of time in which doctors and indeed guidelines were recommending post-menopause hormone therapy for women, and subsequently those recommendations were changed?

A. Only vaguely.

Q. Okay. That's not a case study that --

A. No.

Q. -- you've been through in either school or in any sort of conference?

A. I went to pediatrics, and so by, you know, 1995 I was really in pediatrics and frankly not yet myself in menopause. So...

Page 103

Q. Not a focus of concern. Fair enough. I didn't mean to get personal.

A. That's all right. I brought it up. Sometimes that's what you pay attention to.

MR. BROOKS: I'm going to ask the reporter to mark as Exhibit 10 a document bearing Bates Numbers BOEAL_WPATH_91211 through 91218, which is an email dated February 23 -- February of 2023, February 7, attaching a "Draft 12-point Strategic Plan," and designated confidential. Let me be clear on the record.

(Document marked as Lightdale Exhibit 10 for identification)

MS. LEVI: Roger, we're going to designate the transcript as confidential.

MR. BROOKS: And I will ask you to follow up with specific designations within that. I think this may be the only confidential document we'll look at.

MS. LEVI: Okay.

Q. Dr. Lightdale, I'm confident you have not seen this before.

A. No.

Q. I will represent to you that discovery and

Page 104

indeed testimony last Friday has confirmed that the 12-point plan was written by Dr. Coleman, Eli Coleman. Is that a name that means anything to you?

A. No.

Q. I will also represent to you that he was the chair of both the SOC-7 development project for WPATH and the SOC-8 development project. He's testified about the substance.

I want to take you, though, specifically to Page -- and he's testified that he is the author of this entire 12-point plan written in February of 2023. My representation.

I want to take you to Page -- we call these things at the bottom production numbers or Bates numbers -- ending in 216.

A. Okay.

MS. LEVI: It ends in 216.

THE WITNESS: Okay. Got it.

Q. And actually, the sentence at the top of the page begins at the bottom of 215 where he wrote, "As a result our methodology evolved and was improved - however, we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."

Page 105

Do you see that?

A. Yes.

Q. Now, the chairman of the SOC-8 project has written, after the completion of that project, that the team did not use GRADE explicitly.

Do you have any basis to disagree with him in that regard?

A. Obviously, I'm, like, just looking at this thing. But that is what is written there.

Q. He goes on to say, under "Research Agenda" -- pardon me. Let me just draw your attention to the first full paragraph on the page ending in 216, where he says, quote, "I think it would be helpful to engage a guideline development expert or experts to examine what we have done and help us form a clear narrative and justification for what we have done." And he goes on a little farther to say, "We need to sharpen our method about strengths. At the same time, we need to know its limitations."

Do you see that?

A. Yes.

Q. Do you consider it good practice to develop and publish guidelines and afterwards bring in an

Page 106

expert to help you know the limitations of what you've done?
MS. LEVI: Object as to form.
A. I think I need to understand the context of this. Is he talking about -- "We were not able to be as systematic as we could have been," is he talking about SOC-7, and now they're trying to say how are they going to improve things with SOC-8?
Q. If you look at the beginning of that paragraph, I believe -- this is my understanding, not a representation -- that this is discussing what was actually done in SOC-8.
A. Okay. Yes. So --
Q. Do you want to hear my question back?
MS. LEVI: And also you should take the time if you need to review the document.
THE WITNESS: Yeah, yeah. Let me understand where this is, because obviously I'm, like -- I don't know timelines, et cetera.
A. (Reviewing document)
Q. As far as timeline, I will represent to you that this is written after SOC-8 has been published.
A. Okay. (Reviewing document) Can you repeat your question.

Page 107

Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used?
MS. LEVI: Object as to form.
A. To be honest, there could be even more rigor around what happened. But as I'm reading this -- and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did.
But if you try, and even -- I feel like even in -- you've been giving me some of this GRADE stuff. There is this concern -- and I think I wrote about this in my own thing -- there is this concern that GRADE itself, especially in pediatrics, can lead us to almost not give the right strong recommendations we need to, because we just don't have the evidence that GRADE is assuming is on the table, and most of what we do in pediatrics doesn't have that type of evidence.

Page 108

So what they seem to be saying here is that Hopkins was helpful, but also constraining, and it's like, "Oh, maybe we could have gone about this a different way."
And so now they're saying, you know -- I mean, he's saying, "We're being attacked for the methodology." Obviously I'm sitting here today trying to understand what we're being asked -- but they said, "Okay, how can we continue to think about what we've done."
So I don't think it's wrong to bring in somebody to say, "Okay, here's what we've done. What do you think of it? And can you" -- you know, I guess here they're saying, "Can you help us feel good about what we did, because we were trying to be as robust as we possibly could be," which takes a lot of work.
Q. Understood.
MR. BROOKS: Let me ask the reporter to mark as Exhibit 11 a paper by Taylor and others entitled "Clinical guidelines for children and adolescents experiencing gender dysphoria," dated 2024.

Page 109

(Document marked as Lightdale Exhibit 11 for identification)
Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions.
Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II -- well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines."
Now, you looked at a methodology web page, but just to be clear on the record, you have not undertaken any attempt to apply the AGREE II methodologies -- or I should say criteria -- to evaluate the WPATH guidelines, correct?
A. Correct.
Q. Nor any other guidelines relating to treatment of gender dysphoria in minors?

Page 110

A. Correct.
Q. Okay. Then I will not ask you to read that one.
And certainly you have not attempted to evaluate the body of evidence relied on for any recommendation in SOC-8 to form your own view as to whether that body of evidence is strong, moderate, weak or very weak, have you?
A. No.
Q. Do clinical practice guidelines themselves constitute scientific evidence?
MS. LEVI: Object as to form.
A. No, not per se.
Q. I will not take your time further with that document.
MR. BROOKS: I'm goings to ask the reporter to mark as Exhibit 12 a paper, the first author Saunders and the last author Lightdale -- you've moved into the senior slot there -- entitled "Patient safety during procedural sedation," and it goes on, published in BMJ --
Q. Am I correct that's the British Medical Journal --
A. Yes.

Page 111

MR. BROOKS: -- in 2017.
(Document marked as Lightdale Exhibit 12 for identification)
Q. And, Dr. Lightdale, for context, am I correct that the BMJ is really in the very top tier of respected medical journals in the world?
A. I would like to think so. I felt that about getting the paper accepted.
Q. That's nice to say, but more generally, am I correct that it is widely recognized as one of the most respected medical journals?
MS. LEVI: Object as to form.
A. Uh-huh.
Q. And explain to me the nature of your involvement in this paper.
A. So I served as the senior author on this paper that involved several experts, as well as myself, in a particular monitoring technique called capnography that clearly shows -- I mean, there are many studies out there that have shown that it can pick up patients who are starting to desaturate in terms of oxygen. But, thankfully, none of the studies alone have been big enough that anybody has become truly injured or died, you know, real patient

Page 112

safety discussions.
So it was doing a systematic review of anything out there, and then a meta-analysis of the randomized controlled trials that did exist around capnography, to begin to understand just how big a study you'd need to do to show somebody dying, basically, and in the process also showing, across all the studies, that monitoring with capnography does lead to less oxygen desaturation.
Q. And so underlying this paper, your team did a formal systematic review?
A. Yes.
Q. And you disclosed the -- I'm not even sure of the right term, but the PICO, population -- I think you said it earlier, but can I get you to spell out what PICO stands for.
A. PICO is the population, the intervention -- what's the C -- and then O is outcomes.
Q. All right. And did you make available, either in the paper or in publicly available supplemental material, evidence tables?
MS. LEVI: Object as to form.
A. The truth is, I don't remember. I will tell you the first author, who I worked with very

Page 113

closely on this, was a -- he's not a physician. He just does health economics and systematic reviews.
Q. On Page 2, you identify -- let me take you down to the "Methods." You identified which databases you searched in, correct?
A. Yes.
Q. And there's only three, but are these three so extensive that that represents a rather comprehensive search?
A. Yeah.
Q. And it goes on to say that the searches aimed to identify, quote, "all literature reporting on randomized, controlled trials," close quote.
Let me ask, why did you limit the search to controlled trials?
A. So at the time that we did this, there had, at that point, been a number of randomized controlled trials on capnography. I was actually the first to do a randomized controlled trial of capnography, and people didn't want to put it into their guidelines, which was frustrating for me at the time. I was very young and idealistic. I thought it would be a New England Journal of Medicine paper, but it wasn't, it was pediatrics. It

Page 114

was okay. I learned a lot.
But I will tell you then people when on and used my methodology and tried randomized -- you know, did randomized controlled trials in a number of other populations. And this study took basically any randomized controlled trial we could find and was able to do a meta-analysis, so look at all the data across all the different trials.
Q. Is it in fact the case, in your judgment, that uncontrolled studies are known to be at risk of serious bias as a result of effects such as the placebo affect or confounding variables?
MS. LEVI: Object as to form.
A. So study design is obviously critical to trying to get at whether or not intervention is going to be -- you know, can lead to the clinical outcome you're looking for. And there are different study designs you could use to try to mitigate bias.
I think the randomized controlled trial design in this question was able to get away from the question of bias in terms of there are other ways to assess whether or not a patient's in trouble.
So, really, you had to do a randomized

Page 115

controlled trial in a creative way, which, again, I was able to come up with a methodology that then other people were able to use, where you could sort of still have all the regular ways of monitoring patients -- nobody wants to have a procedure without being monitored to make sure they don't, you know, die -- and so we basically needed a randomized controlled trial to get at the question of whether you needed to add capnography in as another means of monitoring to get even safer.
Q. My question was perhaps simpler, which is, isn't it the case that it's well known that uncontrolled studies are at risk of serious bias as a result of effects such as confounding variables or the placebo effect?
A. No, not necessarily.
MS. LEVI: Object as to form.
THE WITNESS: Oh, sorry.
MS. LEVI: Just give me a second.
Object as to form.
A. No, no. Not necessarily. In fact, there are all kinds of ways now of designing trials that are not randomized controlled trials that -- so I guess are uncontrolled trials -- that are, you know,

Page 116

that are equally good at mitigating bias. So...
Q. Equally good?
A. Yeah. Maybe even better. So randomized controlled trials can introduce systematic biases if you're not careful. I mean, just because something is controlled doesn't mean it gets away from, you said, the placebo effect or other things like that. It doesn't -- it's one way of designing a trial to try to mitigate that, but there's lots of ways to do it.
Q. It says, a little bit lower down, quote, "'Grey' or unpublished literature (including Congress abstracts) was included in the search strategy."
Do you see that?
A. Yes.
Q. Now, am I correct that grey literature are publications that are -- have not been peer reviewed? Is that what the term refers to?
A. There is a definition for it, but, you know, for me, it's -- yes, for me, it's stuff that hasn't yet gone through the peer review process.
Q. Why did you consider it appropriate to include grey literature in your search, if it has

Page 117

not yet been through the peer review process?
A. So this particular paper, we were determined to be as inclusive as possible and include anything that was out there that hadn't yet made it all the way to publication.
Q. And is it in fact commonly done, in systematic reviews, to include grey literature?
A. So actually, in one of the papers that you showed me from the GRADE chapters, they actually talk about it. But, yeah, I mean, it's an option. You can include grey literature if that's appropriate for your question.
Q. If you turn to -- well, turn -- the second column on Page 2, towards the bottom is a heading "Quality and potential bias." And there there's a reference to using a modified Jadad score, because we didn't have enough scores already.
What is the Jadad score?
A. You know, this was something that Roger Saunders actually introduced to me. But it was a way of looking at studies and deciding how they -- you know, how to assess them. So it's just another way of assessing evidence, if you will.
Q. It says in the second sentence there,

Page 118

quote, "The Jadad score assesses studies based on their design (randomized and blinded) and their reporting (all patients accounted for), with a maximal score of 5... and a low score of 0."

Am I correct that the Jadad system rates more than simply whether it's randomized or blinded and whether all patients are accounted for? Those are just examples?

A. I think the Jadad score is a very specific way of trying to assess a clinical trial design.

Q. Okay. Why is it important, in clinical trial design, to know whether all patients are accounted for in the experiment outcomes?

A. Sorry. Can you repeat that question.

Q. Yes. I'm just referring to the parentheses -- the parenthetical that says "all patients accounted for." And my question is, why is it important, in evaluating the strength of a study, to know whether all patients are accounted for?

A. Maybe I'm missing this. (Reviewing document) Oh, "and their reporting."

I mean, I think you would -- it may or may not be important. It's just -- again, the Jadad score was a way of saying, "We're looking at a

Page 119

series of studies, and how do we want to rate those studies?"

And, you know, you can -- we did this big literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or -- I mean, you're trying to decide how to think about those in -- all together.

I mean, that reporting is saying -- one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So...

Q. Well, let me break out a little more detail.

MR. BROOKS: Let me ask the reporter to mark a paper "Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Dr. Jadad and others from 1996.

(Document marked as Lightdale Exhibit 13 for identification)

Q. Dr. Lightdale, all I can say is this paper by Dr. Jadad sets out a method of evaluating. Whether it is the only paper by Dr. Jadad on this topic or the latest, I can't say.

Page 120

Do you know one way or the other?

A. I know nothing. All I'm thinking is that this is 1996. So we talked about my medical school graduation. This is as we're all trying to understand is it important or not.

Q. Right. Okay. Fair enough.

It appears to describe the Jadad score system that was referred to in your paper --

A. Okay.

Q. -- albeit introduced to you by one of your co-authors, I think you testified. And as you say, in the introduction, this paper by Dr. Jadad, Exhibit 13, begins "The use of reliable data to support medical and public health decisions is essential."

And am I correct that you've been telling me that this was essentially a new focus of medicine about the time you were graduating from medical school?

A. Yes.

Q. Okay. If you turn to Page 11 -- you will see that we are now in the Appendix, which is "Instrument to Measure the Likelihood of Bias," and we see on Page 11, "Guidelines for Assessment." And

Page 121

as you said, it's very narrow. It focuses on randomization, blinding and withdrawals and dropouts.

Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts.

A. (Reviewing document) Okay.

Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study?

MS. LEVI: Object as to form.

A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself -- it's just another way to think about what happened with the trial.

And in 1996 they said, "Gee, maybe we'd better pay attention to is it a trial where, you know, people withdrew, and have they explained that." And that would seem just logically important.

Q. Why?

A. Well -- so put yourself back in 1996, when we're first starting to realize, "Hmm, maybe we need to pay attention to evidence." And you have, like,

Page 122

a whole -- I mean, it's incredible, right? We were practicing medicine.

Q. You're really harsh on the medical field. But go ahead.

A. It's true. It's how I was taught, you know. It's like nobody was saying, "Where's the evidence?" And now we're starting to say, "Oh, maybe we need to notice this."

So you can potentially have a trial where, you know, the intervention leads everybody to, let's say, I don't know -- like, it's too much. That's a classic one that will happen, where it's just -- and sometimes it's not the intervention. Sometimes it's the study itself was designed in a way that is so impossible for people to do: Come three times a week from, you know, wherever you are in order to do something.

People may simply not be able to do that for a sustained period of time. And that, alone, can lead to lots of dropouts, never mind the treatment itself.

So I think understanding what is it, why were there dropouts, why was there withdrawal is sort of now something we take for granted. But in

Page 123

1996 Dr. Jadad is saying, "Let's pay attention to this. This could be a piece of how to think about a high quality study; not just did it happen, but did someone explain to me why it happened."

Q. If you had -- and this is purely abstract. If you had a study -- let's say it's a two-year study; it's going to go on for a while -- and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically -- and you just looked at the results for the 50 percent who remained.

Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an inaccurately negative understanding of the effect of the treatment, correct?

MS. LEVI: Object as to form.

A. I mean -- I don't know. I think that it's very -- it's so hypothetical.

So I think what's important is to notice that only 50 percent of the people finished the trial and to be asking questions why. And if we

Page 124

don't do that, we don't understand what we got out of the trial.

And so, again, that concept is brand-new in 1996, you know.

Q. Let me flip it, flip the hypothetical, and let's drop it to 30 percent --

A. Okay.

Q. -- 30 percent who don't -- who just, over the course of the study, stopped coming back for -- maybe it's because it was a hassle, maybe it's because they benefited, maybe it's because it hurt them. We don't know. We have no information on why they dropped out.

One thing that could be the case is that they have -- the treatment has made them feel really sick, and they just don't feel like doing it anymore. They're upset, and they don't want to follow through.

In that case, if you looked only at the results for the 70 percent who kept coming, you might get an unduly optimistic reading on the effect of the treatment; am I correct?

MS. LEVI: Object as to form.

A. So once, in 1996, we started paying

Page 125

attention to the fact that, "Oh, people withdraw or drop out of studies," we started coming up with statistical approaches to what you do to avoid that particular, what you're bringing up, concern.

So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right --

Q. Right.

A. -- when you're trying to understand a paper.

But actually there are methodologies that you use -- they call them intention-to-treat methodologies -- where you're going to basically, if someone doesn't finish, that actually will go against the study finding. So you're designing a study and weighing it in a way that you're being very conservative.

And so now I'm looking to understand, was it an intention-to-treat methodology, were there other statistical ways that somebody tried to account for the fact that not everybody is going to finish the study.

Page 126

And I think these days we design trials knowing not everybody is going to finish. So you have to say, a priori, what you are going to do to make sure that you don't bias your own study by being left with your 70 percent.

Q. Okay.

MS. LEVI: We're close to noon. I'm not asking for a lunch break, but it would be good to take another break.

MR. BROOKS: Yeah. And my recommendation would be we take a break, we do one more run, because stopping at noon always makes the afternoon rough.

MS. LEVI: Yeah.

MR. BROOKS: So, yeah. Now is a fine time to stop.

(Recess)

MR. BROOKS: Let me ask the reporter to mark as Lightdale Exhibit 14 a paper from 2001 titled "Effects of Intravenous Secretin on Language and Behavior of Children with Autism."

(Document marked as Lightdale Exhibit 14 for identification)

Q. And, Dr. Lightdale, is this a paper on

Page 127

which you were the first author?

A. Yes.

Q. Indicating that you did most of the hard work?

A. Yes.

Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly.

The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct?

A. Yes.

Q. And that, according to the very beginning of the abstract, was due to simply a three -- a paper that described the experience of three children -- correct?

A. Yes.

Q. -- and parental reports specifically about the supposed effect of intravenous secretin on the language skills of those three children.

A. (Nods head)

Q. And that's not quite a one-patient case

Page 128

study, but it's an extremely small sample, correct?

A. Yes.

Q. And your goal, it says, down in "Objective" a little farther in the abstract, is to apply the scientific method to assess the reproducibility of those reported effects, correct?

A. Yes.

Q. And can you explain to me the distinction between the scientific method that you're referring to here and -- obviously you've described earlier there's been a published paper describing these three children's experiences.

What's the difference between that paper that existed and the scientific method that you referred to under "Objective"?

A. Can I take a look at it? I haven't seen it in a long time.

Q. Of course you may.

A. (Reviewing document) Okay. Because I did not remember that that was my objective. But I am now, why did we phrase it that way?

What was your question?

Q. Again, the beginning of the abstract, and I didn't read it all, but it points out that this case

Page 129

study of three autistic children was based on reports from their parents over a five-week period, right?

A. This was an extraordinary moment in my life, but -- I will tell you, I was very junior. So the senior author is a long-time mentor of mine.

Q. I understand.

A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay."

And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped.

And we said, "Well, what do we do now?", because we were in the middle of our design. And we decided that you could say that what we were doing was still important because of the scientific method, which means that you really ought to be careful before you move to a randomized controlled trial. You need to perform first an open-label trial, and the goal was to basically try to be more sensitive in what we were measuring.

Page 130

So the open-label design, smaller study, open label, allowed us to do a whole lot of different measures on these kids that you could not do in a randomized controlled trial, which is bigger and wasn't based on -- it didn't have even the right data to even do a sample size determination, is my memory.

So, you know, we felt that they had moved too quickly to the randomized controlled trial, and we could make the argument that our study was still important.

Q. So let me focus on one thing you just mentioned.

If you turn to Page 2, the top of the second column is a paragraph that begins, "To formally answer these questions, it seems necessary to observe the basic principles of scientific method by prospectively investigating the reproducibility of the reported effects," correct?

A. Yes.

Q. And what were you referring to as "the basic principles of scientific method"?

A. So -- I don't actually quite remember exactly, but I think the scientific method would

Page 131

state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it.

And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this.

So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So...

Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating."

A. Uh-huh.

Q. Why was it important -- why do you consider that prospective investigation rather than, for instance, a retrospective analysis is among the basic principles of the scientific method?

A. It's funny, because I am not sure I can tell you exactly what the scientific method is anymore. It feels almost like something one does learn in medical school or even in college.

Page 132

But I can answer the question of why prospective data can be important in a moment like this.

Q. All right.

A. So, without a doubt, retrospective data is going to be limited in different ways, because you can -- you can only look at what was reported.

And, of course, if the retrospective data involves, you know, basically, in this case, parents describing that things have changed, there wasn't necessarily good data captured on the baseline before something happened. So all we're getting is, after the fact, somebody saying, "Oh, something has changed."

Prospectively we could really measure the kids at their baseline, and then we could give them the secretin, and then we could say, "Did something change?"

Q. Okay. And looking at that, let's turn to Page 3. There's a section headed "Measures," and there you state that "Children's language level was assessed using the PLS-3."

Is that a well-recognized, objective measure of language skills?

Page 133

A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way.

Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills?

A. My understanding is it's a validated scale.

Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills?

A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed.

Q. And it did not, am I correct, depend on parental reports?

A. Yeah, it's basically -- it's a very -- I don't really -- again, I was not the person administering these particular scales. But basically, they were -- you know, we were going to do a number of different measures, and one of them was this PLS-3 was decided as the best measure.

Q. And if we look at the second column on Page

Page 134

3, it says, in the first full paragraph, "Language and behavioral measures were repeated at T2 to T5."
A. Where are you now?
Q. It's the first full paragraph at the top of Column 2 of Page 3.
A. Oh, I see. Okay.
Q. And noticing the word "repeated," am I correct that part of your protocol was that you did this objective test of language skills at each of T1, T2, T3, T4, T5?
MS. LEVI: Object as to form.
A. Yeah, so, in full disclosure, I haven't really thought about this study in a very long time. So I don't quite remember the whole bits to it. I more remember what was going on around it.
But -- so I would have to honestly get into this a little bit.
Q. Well, let me ask about --
A. I mean, I can read it if you want --
Q. No. Let me ask --
A. -- to see what I wrote.
Q. Let me ask some big picture questions and see if you recall at the big picture level.
A. Yes.

Page 135

Q. If you turn to Page 4 --
MS. LEVI: If you want to take time to review your study --
MR. BROOKS: That's certainly true.
MS. LEVI: -- you should feel free --
THE WITNESS: It's weird to see --
MS. LEVI -- to take the time you need.
THE WITNESS: -- my own words. It's, like, very, very --
Q. I'm going to try back up to the high level, and then you decide what you want to read.
A. Okay. Sounds good.
Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and observable improvement in the sample."
Do you see that?
A. Yes.
Q. And it says -- goes on to say that "70 percent" of parents "reported moderate to high change."
Do you see that?

Page 136

A. Yes.
Q. And -- I'm sorry, I've taken things out of order. If you back up to the bottom of the second column on Page 3, it states, "Analyses revealed no significant increases in children's language skills from baseline following a single infusion of secretin," correct?
A. Yes.
Q. Do you recall, at least, that the big picture take-away from this paper was that secretin did not improve children's language skills and parents thought it did?
MS. LEVI: Object as to form.
A. My own -- when I tell the story of this paper, the big take-away was secretin did nothing.
Q. But am I correct that another important take-away was, notwithstanding it did nothing, that many parents thought it was having a beneficial effect on their children?
MS. LEVI: Object as to form.
A. The answer for me is, I didn't remember that piece of it, but it is there.
Q. Okay. If you turn to Page 5, Column 1, about an inch from the top, a sentence begins, "This

Page 137

pattern of parental response." Do you see that?
A. Uh-huh.
Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence."
So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate?
MS. LEVI: Object as to form.
A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being asked, there's this added level of, well, we don't know what it means.
So you have to take, you know, basically reported -- self-reports and then parental reports of children's behavior just have to be held as a different type of evidence.
It's funny, because reading even the next

Page 138

line -- this was an extraordinary moment going on, but there was a hysteria. And so we knew that part of what was happening is parents at that point were not thinking it was a single infusion; they were now wanting multiple infusions.

So, you know, these are strong emotions people are having, and they're ready to say things, you know.

Q. Well, are there --

A. And it just -- I think what we were saying is, "You have to do this well." If we're going to start talking about cures for autism, they have to be designed very well.

Q. Are there recognized reasons why self-reports and parental reports are commonly unreliable?

MS. LEVI: Object as to form.

A. I mean, I think it's human nature not to be able to objectively think about things. I mean, it's part of being human.

So, you know, anybody makes a big -- I don't know -- in this case says, "We've got a cure for autism," based, you know, on self-reports only, that would not be sufficient to move forward.

Page 139

And I think at this point -- we were contributing at this point to a body of evidence, saying, "This is not a cure for autism, this secretin."

Q. And is the end of the story a broad medical conclusion that secretin did not help?

A. Yes.

MS. LEVI: Object as to form.

THE WITNESS: Sorry.

MS. LEVI: Make sure you give me a chance --

THE WITNESS: Apologies. I'm working on it.

Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" -- let me start again. Pardon me. I'll skip over that. It's too hard to package.

I have put back in order your exhibits, and I'm going to ask you to find Exhibit 5 again, which is -- you can check me on this -- the methodology appendix to SOC-8. Sorry. We've got all sorts of numbers.

If you turn in that document back to

Page 140

Appendix A on Page S247, two inches down on the first column, it says, "The process for development of the SOC-8" -- let me see if you find that.

A. Okay.

Q. "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process," and it then cites a document from the Institute of Medicine and from The World Health Organization.

Do you see that?

A. Yes.

Q. Are you, yourself, familiar with a document from the National Academies of Medicine or the Institute of Medicine that sets out procedures for developing guidelines?

A. I am familiar with it. It's a big document. It's a book.

Q. Have you, yourself, consulted that -- such a document from the Institute of Medicine?

A. Yeah.

MR. BROOKS: Let me ask the reporter to

Page 141

mark as Exhibit 15 a document published by the Institute of Medicine entitled "Clinical Practice Guidelines We Can Trust." And I believe that this is selected chapters of, as you say, a whole book.

(Document marked as Lightdale Exhibit 15 for identification)

Q. Let me ask you to take a look at this. And recognizing it is the cover page, the table of contents and then selected chapters, does this appear to be portions of the book that you have in mind?

A. Yes.

Q. And you've cited this yourself, have you not?

A. Yes.

Q. And is this a widely respected set of criteria for good practices for developing guidelines?

A. I think it's an important text in the field, yeah.

Q. Is there any other that you consider to be more authoritative in terms of good practice for developing guidelines?

A. I mean, I'll just note it was 2011. We've

Page 142

already changed things a number of time. I mean, you really have -- in fact, you've brought it out. We have AGREE II which comes out much later.

So at that time, in 2011, it was really helpful that they created this text that you could reference.

Q. Do you know whether the Institute of Medicine has publish any more updated version of this?

A. I don't think so.

Q. And we've seen together that this was cited in the SOC-8 methodology, correct?

A. Yes.

Q. Do you believe that accepted good practice for developing guidelines has become, shall I say, tighter, more rigorous since 2011?

A. Yes.

Q. Not less?

A. Become tighter. Yes.

Q. In your report, which we've marked as Exhibit 4, you wrote, in Paragraph 19 on Page 6, quote, "WPATH's process for developing SOC-8, as described at," and then you have the -- you have a live link, actually, to the web page in question,

Page 143

right? -- "is transparent, rigorous, and methodologically sound."

Do you see that language?

A. Yes.

Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct?

A. Right.

Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development.

A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers.

So you want to, I think -- in a very general way, the most important transparent thing is to say how you -- you know, what you were looking to do and how you did it. And then, from there, transparency plays out in lots of other ways. So...

Q. Provided that the team was careful and rigorous, why does it matter whether they're transparent?

A. Is that kind of my opinion? I don't

Page 144

that I can --

Q. Here you are. You're an expert, here to offer opinions.

A. I'm the expert, okay.

So I think we're all learning, still, as we go. And so the transparency gets important, because I need to understand, as a, you know, physician or somebody who's going to potentially going to use a guideline, how did it happen?

And actually in some ways it goes along with -- like, I think we've talked a little bit about this, but there was that discussion how AGREE II starts talking about the funding source, right? So we need to understand who is driving the guideline, why is it happening, how did they do it.

And so that transparency has actually become really important. And it's been a piece of evolving and, again, something we're continuously improving. I don't think anything's done yet. I bet there's an AGREE III in a couple of years.

So, you know, it's just, like -- it's constantly trying to get guidelines better. Is that okay?

Q. Let me ask you to find that Institute of

Page 145

Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42.

A. Hold on.

MS. LEVI: I think it's this (indicating).

Q. This is what it looks like (indicating).

A. Sorry. This one.

Q. And if you would turn to 42.

And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health?

A. National Association of -- National Academy of Sciences.

Q. National Academy --

A. -- of Sciences.

Q. Is it governmental entity?

A. It is not, technically. It's, like -- it is and it's not. So -- or I don't know. I don't actually -- and I'm not in it is the truth.

Q. Let's not spend time parsing out it is and it's not.

Let me ask you to turn to page, what did I say, 42, and --

A. I think -- if you don't mind, I think the

Page 146

government commissions it.
Q. Okay.
42 begins, "Organizations in several countries outside the U.S. also produce clinical practice guidelines."
And it goes -- in the next paragraph it begins, "For example, the National Institute for Health and Clinical Excellence (NICE) is an independent organization that advises the UK National Health Service," and it continues.
Are you familiar with the reputation of the UK NICE?
A. I know what the NICE is.
Q. Is it a respected source of analysis of medical science?
MS. LEVI: Object as to form.
A. Respected by who, I guess? Like, by Americans? We don't necessarily follow NICE stuff.
Q. Well, what does NICE do, to your knowledge?
A. Okay. So this is purely what I understand.
Q. That's all you can ever testify to.
A. But the UK, unlike the United States, in around -- actually, around as I'm graduating from medical school, forms the National Health Service

Page 147

and puts in place, over time, this National Institute for Health and Clinical Excellence, the NICE, which basically -- that's what I call it -- which basically comes up with standards of care and guidelines that go across the UK.
Unfortunately, the United States didn't have that. So we have had a system that hasn't had single payer like the National Health Service, and instead we have allowed guidelines -- or we've actually basically made it in the United States that if you're going to have guidelines, it's all these independent groups that have to create them.
And so guidelines in the U.S. are not coming from a -- you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean, everybody is doing their own guidelines. So...
Q. The next sentence in this second full paragraph gives a little more detail about the functions of NICE. It says, quote, "It conducts or contracts for technology assessments of new treatments and devices as well as systematic reviews and comparative effectiveness studies used to

Page 148

produce clinical guidance."
Were you aware, before reading that, that NICE conducts or contracts for systematic reviews?
A. What I -- I didn't know that specifically. What I knew --
MS. LEVI: That was the question.
Q. That was the question.
A. Okay.
Q. So you don't have any view as to the reputation of NICE for performing thorough or reliable systematic reviews?
A. No.
Q. Okay.
Do you agree that transparency in the development of a -- appropriate transparency in connection with a clinical practice guideline includes disclosure of the design of any systematic searches that were done, for instance, the PICO criteria?
MS. LEVI: Object as to form.
A. Actually -- I apologize, because I am getting a little tired. So can you repeat that question?
MS. LEVI: Do you need a break?

Page 149

THE WITNESS: Maybe. Maybe.
MS. LEVI: It's perfectly fine.
MR. BROOKS: We can break for lunch now.
MS. LEVI: Okay. Why don't we do that.
MR. BROOKS: Fine.
THE WITNESS: Is that okay?
MS. LEVI: Of course. Absolutely. You get to -- absolutely.
THE WITNESS: Okay. 12:40. I might have hit my, like, lunchtime.
MR. BROOKS: That is just fine.
MS. LEVI: It is close to 12:45. Shoot for half an hour?
MR. BROOKS: That's fine.
(Luncheon recess taken at 12:42)

Page 150

AFTERNOON SESSION 1:20 p.m.
MS. LEVI: I will take a rough. A couple days is fine.
BY MR. BROOKS:
Q. Let me ask you, Dr. Lightdale, to find Exhibit 15, the "Clinical Practice Guidelines We Can Trust." If you would turn in that document to Page 2, which is a ways in, because it follows the preface.
On Page 2 is the heading that says, "CPG," Clinical Practice Guideline, "Development Challenges." And an inch and a half down, two inches down in that is the sentence that begins, "Certain factors commonly undermine." Let me ask you to find that.
A. Yes.
Q. It reads, "Certain factors commonly undermine the quality and trustworthiness of CPG's." And you understand that to refer to clinical practice guidelines, correct?
A. Yes.
Q. And it goes on to list factors that undermine quality and trustworthiness, including "lack of transparency of development groups'

Page 151

methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest."
Do you see the various things I've pointed to?
A. "Unmanaged conflicts of interest." Yes.
Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors?
MS. LEVI: Object as to form.
A. I think this is a list of things you have to be thinking about, and there's not any one absolute. So I'm not sure I totally agree that that's how one defines a good clinical guideline.
Q. You would consider, would you not, that appropriate transparency in connection with the development of a clinical practice guideline will, in fact, include disclosure of the systematic

Page 152

searches that were done for scientific evidence?
MS. LEVI: Object as to form.
A. I think I need to understand better what the -- like, what's not a systematic search, or whatever.
I'm not sure exactly how to answer that, because I think there's a lot of things you think about when you're looking at clinical practice guidelines. That's what I think this paragraph is saying: There are a lot of things you have to think about.
Q. I'm asking your opinion now, not what the paragraph is saying.
If a group preparing a clinical practice guideline performs systematic searches for relevant evidence, do you agree that appropriate transparency includes disclosing the nature of searches done?
MS. LEVI: Object.
A. So I think it's just -- again, for me, these are, like, sort of abstract questions, and I would need to get more specifics, I think, in order to understand what we're trying to get at here, is the bottom line.
So for me, there's lots of things you're

Page 153

thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline.
Q. Let's see if you want to stick with that.
* Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence?
MS. LEVI: Object.
A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases?
Q. No, that wasn't my question.
MR. BROOKS: Let me ask the reporter to read back my question.
(* Question read)
A. I would say not in and of itself. That's not the only definition of transparency.
Q. I didn't ask if that was the definition of

Page 154

transparency. I asked you whether good practice includes disclosing the databases that you searched for relevant evidence.
MS. LEVI: Object as to form.
A. I'm getting lost in the question, but not in and of itself is listing the places you searched.
Q. Would you agree that good practice in connection with preparing a clinical practice guideline includes, if the team has used established criteria for rating the strength of evidence, disclosing the ratings that were assigned?
MS. LEVI: Object as to form.
A. I think there are lots of ways to do guidelines. So the important thing is that you basically put out what your process is going to be, and then you follow it.
Q. That's it? That's the sum total of your opinion as to what constitutes good practice in forming and creating a clinical practice guideline?
MS. LEVI: Object as to form.
A. I think there are now lots of groups, including this group and including other groups, that are saying, "Okay, let's go through different ways of measuring guidelines in trying to decide."

Page 155

But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline.
Q. So it's just kind of a gut check?
MS. LEVI: Object as to form.
A. I think it's complex.
Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed?
MS. LEVI: Object as to form.
A. I'm not sure what you mean by "results of the systematic reviews." Like, what is that "results of the systematic reviews"?
Q. You have performed systematic -- you've participated in performing systematic reviews?
A. I have.
Q. And how would you describe the output of what is now recognized as a formal systematic

Page 156

review?
A. So when I have done systematic reviews or been a part of systematic reviews, generally we've worked with somebody who's performed the systematic review for us, usually a librarian.
And then what you've got is, Okay, we were given this number of papers that might or might not meet our criteria, and then we've gone through and we've made decisions about which ones we're including or not including, and we wind up with, in the end, Okay, we included X number, and then you move from there, where we've reviewed it.
And so you've sort of gone through a process. So the systematic review starts the process, and then you have to move through it. And we've usually explained that in some place, you know, either in a figure or in a paragraph, in text.
Q. * If a team developing clinical practice guidelines has commissioned systematic reviews that resulted in GRADE ratings of the quality of evidence on certain topics relevant to the clinical practice guideline, would you agree with me that it would violate principles of transparency not to make those ratings available publicly?

Page 157

MS. LEVI: Object as to form.
A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were -- you know, didn't realize that it would be important.
I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way -- it's really not where we are. It's just becoming something that people are talking more about.
So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it.
So, again, without getting into the specifics, I can't really understand what I'm going to be commenting on here. So...
MR. BROOKS: Let me ask the reporter to read back my question.
(* Question read)
A. It's a very long question. So there's different pieces to it, and it seems to be ending with, is it violating principle not to put the GRADE

Page 158

ratings next to the recommendations.
Q. No. That's not my question.
A. Okay. So maybe I can --
Q. Does it violate principles of transparency not to disclose those GRADE ratings in any way, shape or form?
MS. LEVI: Object as to form.
A. Not to my knowledge.
Q. If an organization, for the purposes of preparing clinical practice guidelines, commissions an independent team to conduct systematic reviews for the purpose of informing those guidelines, is it consistent with principles of transparency for that sponsoring organization to prevent the publication of the results of the systematic review?
MS. LEVI: Object as to form.
A. Not to my knowledge.
Q. * If an organization preparing clinical practice guidelines commissions systematic reviews on certain topics from an independent team and receives those systematic reviews, is it consistent with ethics and transparency, in your view, for that organization to publicly deny that the systematic reviews were done?

Page 159

MS. LEVI: Object as to form.
A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which -- I mean, I don't know. I'm not exactly sure what this would be.
My understanding is you have an independent group that is now -- has done the systematic review, and the other group doesn't -- wait. You explained something, and you said the first group should now deny?
MR. BROOKS: Let me ask the reporter to read the question back.
(* Question read)
A. Which organization? The one that commissioned it?
Q. Yes.
A. It wouldn't -- you don't have to use a systematic review when you publish your guideline. I actually think, no, that that -- in my opinion, you've done a systematic review, you might say, "Gee, that wasn't good enough," or "That didn't get what we wanted to," or "It didn't" -- "Actually, we forgot a search term. Let's go back and do it again."

Page 160

I mean, there's lots of contexts in which you might make a decision that a systematic review didn't get what you needed and you would go back and do it again.
So if that's what we're asking or -- I'm not sure if that's what you're asking. I think there are reasons that a systematic review is simply not included in the guideline.
Q. That's not what I'm asking.
A. Okay.
Q. If an organization such as WPATH, preparing clinical practice guidelines, commissioned systematic reviews to be performed by a separate entity, those reviews are done and delivered to the sponsoring organization, is it, in your view, consistent with ethics and transparency for the sponsoring organization to publicly deny that the systematic views were in fact done?
MS. LEVI: I'm going to object as to form. And also the question has been asked a number of times.
I just want to say, answer it if you can.
A. Yeah, I guess I'm having trouble understanding what would be the context in which

Page 161

they would be asked, "Did you do a systematic review?", and then they would publicly deny it.
I just don't get what happened here. This would -- this is -- guidelines are not usually any need to deny anything. It's just --
Q. Are you unable to answer your question?
A. I would be unable to answer your question. Not following it. So...
MS. LEVI: You can only answer a question if you can.
THE WITNESS: Okay.
MS. LEVI: It's fine. If not, if you can't answer it, then respond as such.
Q. Let me ask you to find your expert report, which is Exhibit 4.
There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a "well-established methodology." We've talked about it a bit. We've discussed the voting process. We've discussed anonymity. I don't want to rehash all that.
In 23, you quote Dr. Laidlaw as saying Delphi is not, quote, evidence based. Do you see that?

Page 162

A. Yes.
Q. Now, am I correct that Delphi is a process which could be used to achieve consensus or to attempt to achieve consensus on either evidence-based recommendations or recommendations based simply on expert opinion? It could be used for either of those, correct?
A. That's my understanding.
Q. And in one case the output would be evidence based, and in the other case the output would not be evidence based, right?
A. I mean, Delphi, again, is a process for developing consensus.
Q. And using Delphi doesn't tell you anything one way or the other as to whether --
A. Correct.
Q. -- the output is evidence based?
Okay. I just wanted to clarify that.
And you, yourself, have, on multiple occasions, participated in Delphi processes?
A. Yes.
Q. Given the nature of a Delphi process and the importance of anonymity as you've described it, would it be appropriate for the leadership of a

Page 163

clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process?
MS. LEVI: Object.
A. So not -- I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed.
Q. In my question I said "substantive changes."
MS. LEVI: Object as to form.
A. That's what I think you said. So that's what I thought you said.
So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So...
Q. Is your understanding, based on what you read from the WPATH web page, that all the WPATH recommendations and suggestions were approved through a Delphi process?
A. I don't remember if it was all of them, but they were definitely using a Delphi process.
Q. And do you recall seeing anything in the

Page 164

WPATH methodology web page that suggested to you that WPATH leadership made substantive changes to the guidelines after the completion of the Delphi process that they describe?
MS. LEVI: Object as to form.
A. All I read was the website that explained their process. I don't recall anything saying about making any changes after the fact.
Q. As a scientist and clinician, if you read a set of guidelines in which the methodology said that all the recommendations were approved through a Delphi process, and in fact some of those recommendations had been materially altered through a non-anonymous process after the Delphi process, that would cause you serious concern, would it not?
MS. LEVI: Object as to form.
A. Not necessarily. Having been through it, what I would need is an understanding, some context around what changes were made and why.
Q. Why, given the importance of the Delphi process and the anonymity of the Delphi process, do you need more context to form an opinion as to whether post hoc changes through a non-anonymous process would violate principles and cause you

Page 165

concern as a scientist and a clinician?
MS. LEVI: Object as to form.
A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular -- I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process.
So I think there are even allowances within Delphi to be able to keep working after the iterative process is done.
Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again?
MS. LEVI: Object as to form.
A. I personally have not.
Q. Okay.
Let me ask you to find Paragraph 31 of your report. And there you stated, "Dr. Laidlaw also erroneously suggests that merely being a provider who treats gender dysphoria creates a 'conflict of interest' with respect to participating in the development of guidelines. This has no basis in

Page 166

medical ethics or science," close quote.
Now, you would agree with me, would you not, Dr. Lightdale, that being a provider who treats gender dysphoria is likely to give a physician some financial interest in -- some potential financial interest in what procedures are or are not approved by the guidelines?
MS. LEVI: Object as to form.
A. No. No. I don't agree with that statement.
Q. Why is that?
A. I think physicians who treat conditions -- I mean, we're talking here about gender dysphoria, but I treat conditions. I am treating a patient for what they have as a condition. That's what I'm supposed to do as a health care provider.
So I don't think my financial interest is in providing treatment to patients. It's my profession.
Q. I could flip back to it, but let's see if we can do it without.
You recall that we looked at the SOC-8 methodology appendix which had language that stated that that team relied on recommendations developed

Page 167

by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest.
Do you recall that, or do you want to go back to it?
A. I don't --
Q. Let's find the exhibit, which is Exhibit 5.
Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." And then it cites the IOM document that we've looked at, correct?
A. Yes.
Q. As well as a WHO document that I'm not going to take your time with.
A. Okay.
Q. Now, would you agree with me that, while there may be different protocols for dealing with

Page 168

and disclosing and managing conflicts of interest, it's important to transparency that a clinical practice guideline development team does follow the protocols that they state that they followed?
MS. LEVI: Object as to form.
A. So -- right. So I think that there are -- there's a framework here, and there's lots of different ways that I can put that framework into action. But I would say, if you're going to state something, then you followed it.
Q. If you state that you followed it, you should follow it; that's what you're saying, correct?
MS. LEVI: Object as to form.
A. I mean, this is the methods of what they did. So they are describing their methods.
Q. And my question is, if they describe their methods as incorporating recommendations with respect to conflict-of-interest policy from the Institute of Medicine document, then it would violate principles of transparency if in fact they did not follow those conflict of interest principles?
MS. LEVI: Object as to form.

Page 169

A. I think there are lots of ways to do conflicts of interest, and -- I've personally filled out many conflict-of-interest forms, and there are lots of different ways.
I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but...
Q. Maybe it is.
Why don't you find Exhibit 14, the Institute of Medicine --
MS. LEVI: I think that's 15.
MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction.
Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency."
A. Okay.
Q. And on the following page, 77, the paragraph at the bottom of the page begins, quote, "Transparency also requires statements regarding the development team members' clinical experience, and potential conflicts of interest, as well as the guideline's funding source(s)."
Do you see that?
A. Yes.

Page 170

Q. Do you agree with that statement?
A. Sure.
Q. And if you turn to Page 78, you'll see a heading, "Management of Conflict of Interest," and there, in the second full sentence, it states, "A recent comprehensive review of conflict-of-interest policies of guideline development organizations yielded the following complementary descriptions of conflict of interest," close quote, and it goes on to quote two of what it's referred to as "complementary descriptions."
I want to read to you the first. Quote, "A divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams or community standing."
Do you see that?
A. Yeah.
MS. LEVI: Take the time you need to review the document.
Q. My question for you is whether that

Page 171

definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest.
A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated.
So for me -- and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest.
Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind."
And the following sentence says, quote, "Finally, intellectual conflicts of interest specific to clinical practice guidelines are defined as 'academic activities that create the potential for an attachment to a specific point of view that could unduly affect on individual's judgment about a specific recommendation," and it quotes a Guyatt

Page 172

publication.
Do you see that language referring to intellectual conflicts of interest?
A. Yes.
Q. And are you generally familiar with the concept of intellectual as opposed to financial conflicts of interest?
A. Yes.
Q. And you agree that intellectual conflicts of interest can be among the types of conflict of interest that should be disclosed in connection with a clinical practice guideline project?
MS. LEVI: Object as to form.
A. I mean, I would say that is -- that's an opinion, and one I think I've come to. But, you know, it's an evolving area. That's the other thing about that one.
Q. If you look at Page 79, six line down, at the end of the line it begins a sentence as follows, quote, "Direct financial commercial activities include clinical services from which a committee member derives a substantial portion of his or her income; consulting; board membership for which compensation of any type is received; serving as a

Page 173

paid expert witness," and it goes on.
Do you see that language?
A. Yes.
Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income?
MS. LEVI: Object as to form.
A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill -- if I do a particular thing or not, because I'm still going to get the same salary. That's number one.
Number two is the way medicine works. You're getting paid for encounters. You're not getting paid for, you know, doing anything specific. You're just getting paid to see the patient.
And then the third thing is, I don't think that the National Academy of Sciences would have taken us down a route that means that experts in an area can't participate in guidelines, you know, that that would make no sense.

Page 174

So I think we know we need experts in guidelines and that those experts have to really be doing the medicine in order to be able to be a part of that process.

So I think what they're talking about there is, if you are, and I do, do some consulting, or you do have royalties or something like that, that's where you must disclose, on a conflict-of-interest form, that you work with a company that actually has interest in a guideline going in a certain direction.

It's not about the practice of medicine. It's about what you're doing to the side of that that they're worrying about.

Q. Let me break out a couple of things that you said.

First, when it comes to fees for procedures, is it your testimony that, when you perform an endoscopic procedure, that there is not separate billing tagged to that procedure?

MS. LEVI: Object as to form.

A. I mean, I submit a bill, but I myself will get the same salary whether I've submitted the bill, like -- or not. It's not -- I don't have -- like,

Page 175

many of us, particularly in pediatrics and in academic pediatrics, are not -- it has nothing to do with how much or how little we bill. We're going to get our salaries. So...

Q. Let's break that out.

It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure?

MS. LEVI: Object as to form.

A. Our current health care system is absolutely about patient-facing activities being billed.

Q. Specific procedure --

A. Specifically.

Q. By specific procedure?

A. Sure.

Q. Second, it's by no means the case, is it, that all physicians are salaried, such that their income does not depend on how many procedures they perform?

A. This is true.

Q. And you also understand, do you not, that the IOM conflict-of-interest policy in many cases

Page 176

talks about management through disclosure and is not saying that everybody who has a conflict of interest is disqualified from participating in a guideline development process? You understand that, correct?

A. Yes.

Q. Okay. Now, my question for you is, is it consistent with your understanding that a physician, who provides clinical services potentially affected by the guideline from which that individual derives a substantial proportion of his or her income, has a financial conflict of interest of a type that needs management, perhaps through disclosure?

MS. LEVI: Object as to form.

A. I don't think that's what they were trying to get at here. I think they're assuming that the people on a guideline committee are experts in their field and do that type of medicine. So that was -- that's sort of an assumption. There's no point in being in a guideline-writing process if you don't actually practice the medicine.

So I think what they're getting at here is, are you going to be making money because you have stocks in something or you consult for something and you'll get more money if you, you know, continue to

Page 177

consult, and people will be happy with you.

Q. Dr. Coleman -- pardon me. That was Friday.

What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"?

A. I mean, I think -- the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include.

And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income."

And I guess where I'm thinking is that -- what they're talking about there, I think, is someone who is going to make a lot of money if they do something -- I mean, basically the guideline is going to have them do something more, and so then they're going to do more of it, and now they're going to make a lot of money.

I don't -- I just don't think that they're talking about providing clinical medicine. To me,

Page 178

that's -- like, doesn't make any sense. It's about commercialism, and we're talking -- I practice medicine.

So I think what I can understand and what I tend -- what I think of when I fill out a conflict-of-interest form is, if I sit on a board, if I consult, if I've been a paid witness, if I'm doing industry-sponsored research, I have a financial interest in that company, and so then I need to disclose that on the disclosure form.

Q. So as you sit here today, you really can't understand what the IOM was referring to when they talk about clinical services?

A. I think they're talking about clinical services that are affected when you sit on a board or you consult or you -- I think that's what this is all getting at.

It's not getting at do you practice medicine. Like, do I practice pediatric GI? Yes, of course. I sit on guidelines because I'm an expert in that particular area.

So, you know -- and I'm trying to remember where we started this, but financial conflict of interest is not practicing medicine. It's not

Page 179

treating patients. I mean, otherwise, we're going --

MS. LEVI: You answered the question.

Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally."

Do you see that?

A. Yes.

Q. Let me ask you to read that and the following sentence.

A. "A person whose work or professional group --"

MS. LEVI: Did you want her to read it for record or --

MR. BROOKS: Oh, might as well.

Q. Go for it.

A. It's actually easier for me, guys.

"-- fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to have intellectual COI. Intellectual COI includes authoring a publication or acting as an investigator on a peer-reviewed grant directly related to recommendations under consideration."

Q. Is that definition of an intellectual

Page 180

conflict of interest consistent with your understanding?

A. I think so.

Q. And would you agree with me that, under that definition of an intellectual conflict of interest, when it comes to pediatric endoscopy, you have an intellectual conflict of interest?

MS. LEVI: Object as to form.

A. There are areas of my field where I may have intellectual conflict of interest, like within it, that I have -- sure.

Q. Okay.

A. -- strong feelings on things, and I can --

Q. And strong published positions?

A. Sure.

Q. Okay.

* For physicians who are compensated based on the revenue they generate for their practice, is it still your position that those physicians have no conflict of interest, financial conflict of interest, with respect to clinical practice guidelines that may affect their practice?

MS. LEVI: Object as to form.

A. I may need the beginning of the question

Page 181

asked again. Sorry.

(* Question read)

A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking?

Q. Again, we've talked about how IOM -- discussion of conflict of interest doesn't necessarily require exclusion as far as management.

So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice guidelines that may significantly affect that physician's practice?

MS. LEVI: Object as to form.

A. So what I'm having trouble with is, they would have a conflict of interest in terms of participating in the guideline. They probably should disclose, again, that they own a practice

Page 182

where they are doing a lot of the procedure that's going to be recommended in the guideline, or not recommended in the guideline, that their practice will be affected financially by that.

I do believe in conflict-of-interest forms. You can be asked, "Do you own a practice?" I mean, that's -- you know, that's a reasonable thing to ask, "Do you own a company?" I think you get asked that, "Do you own a company?", which private practice technically would be.

Again, for me, the difference is that I don't think this is about being an expert in the field. Like, that's just not one thing -- I'm not asked, when I do these guidelines, "Are you a gastroenterologist who's going to get affected by the guidelines?"

The answer is, of course, "Yes." Like, everybody involved in the process is a gastroenterologist who's going to get affected by the guidelines.

So it's not a financial conflict of interest, what I do. Does that make any sense?

Q. Dr. Lightdale, do you consider yourself to be an expert in conflict-of-interest principles?

Page 183

A. No.

Q. You, in fact -- and I think this follows from your earlier testimony, but let me ask.

Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict-of-interest principles spelled out in this document, Exhibit 15?

A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends.

Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH?

A. No.

Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed?

A. No.

Q. You don't know whether -- you don't know what proportion of the participants in the SOC-8 development project had intellectual conflicts of interest of the type that we've discussed?

MS. LEVI: Object as to form.

A. I don't. I did think it was impressive

Page 184

that they had a process where they asked for both financial and nonfinancial conflicts of interest.

I mean, again, most of us are just starting to do this.

Q. What led you to believe that WPATH had a process that included asking for intellectual conflicts of interest?

A. It may have been talked about -- at some point somebody brought it up.

Q. What do you mean by "somebody brought it up"?

A. Isn't that here (indicating)? I don't remember.

Q. Do you recall seeing any document in which WPATH claims to have identified --

A. Maybe it's in this thing right here, to be honest, that we read it today.

(Reviewing document) I think -- (reviewing document)

I'm actually getting all dizzy right now.

MS. LEVI: Do you want to take a break?

THE WITNESS: Well, yes.

A. But maybe I want to try to understand what we were talking about. Maybe it was way back at the

Page 185

beginning of the morning when we talked about this piece (indicating).

I can't remember. We were talking about -- I know, because I'm really interested in this intellectual conflict of interest discussion. So...

Anyway...

MR. BROOKS: Would you like to take a break?

THE WITNESS: Yes.

(The witness and Ms. Levi leave the room)

THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well?

MR. BROOKS: I would like a rough.

(Recess)

MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context.

THE WITNESS: Yes. So I want to make it clear that, in preparing for today, I had seen a document that was likely a conflict-of-interest document, and I think, again, such stuff I'm interested in intellectually, intellectual conflict of interest around this discussion.

BY MR. BROOKS:

Q. Do you have any knowledge, Dr. Lightdale,

Page 186

as to whether the chair of SOC-8 had either intellectual or financial conflicts of interest relevant -- relating to treatment of gender dysphoria?
A. I have no idea.
Q. And likewise, am I correct that you have no idea as to whether the co-chairs of that project have financial or intellectual conflicts of interest?
A. I don't know that, no.
Q. And the same is true with respect to the chapter leads of each chapter team?
A. No idea.
Q. Just because of law, I'm ticking these things off.
And you have not formed any opinion as to the adequacy of the actual disclosures made by WPATH of conflicts of interest that may exist with respect to any participants in the process, have you?
A. I have no opinions.
Q. You get out of a whole lot of deposition by just saying, "I have no opinions."
MR. BROOKS: Let me ask the reporter to mark as Exhibit 16 an article from 2018 entitled

Page 187

"Evaluating Patient-Centered Outcomes in Clinical Trials of Procedural Sedation, Part 2," authors -- lead author Denham Ward, and many authors, one of whom is Dr. Lightdale.
(Document marked as Lightdale Exhibit 16 for identification)
Q. Dr. Lightdale, I'm going to ask you first if you can identify this paper.
A. Yes.
Q. And can you explain to me your role in its creation.
A. So I was invited to be in this committee -- which was brought together by the FDA, but then represented a whole lot of stakeholders -- to come up with recommendations for what our endpoint -- what endpoints should be around treatment.
This particular paper was around treatment, education and research. So endpoints for trials.
Q. And for the record, for the layman, can you explain to me what you mean by "endpoints."
A. Outcomes, what you could look at in a trial.
Q. The things you're measuring, fundamentally?
A. Right.

Page 188

Q. And this was in connection with sedation generally?
A. Yeah. This was not GI per se.
Q. Okay. Let me ask you to turn to the second page of the document. In the first column, four inches down, there's a paragraph that begins, "SCEPTER's previous study."
Do you see that?
A. Uh-huh.
Q. And what is SCEPTER? It sounds like something from a Bond movie.
A. SCEPTER is Sedation Consortium on Endpoints and Procedures for Treatment, Education and Research. SCEPTER.
Q. Thank you.
Late in the paragraph is a sentence -- and feel free to read the whole paragraph. I'm going to call your attention to sentence that begins, "While safety is arguably the most important of the 6 IOM domains, its measurement in clinical trials presents complex problems and dilemmas."
Do you see that language?
A. Yes.
Q. I'm going to ask you about that, and you

Page 189

can look at anything surrounding you want.
The beginning of the paragraph refers to, I think, a different document from the Institute of Medicine, just to avoid any confusion.
Do you have an opinion as to -- well, are you able to explain to me why it's the case, if it is, that safety is arguably the most important consideration being addressed here?
A. So the group took the tack of saying that we were going to focus on safety, because, I think, when you give sedation and anesthesia, you want to avoid physical or psychological harm, and we thought that was perhaps the most urgent thing you have to think about with sedation, especially for procedures.
Q. Does sedation risk both physical and psychological harm?
A. Yes.
Q. Is one of those considered to be a more serious problem than the other?
MS. LEVI: Object as to form.
A. I think we considered them both. I mean, either was bad.
Q. Okay. And are you telling me that the

Page 190

group simply chose to focus on safety, or is safety, for some recognized reason, the most important concern as physicians evaluate procedures?

MS. LEVI: Object as to form.

A. So SCEPTER was trying to decide what are good things to measure, and safety -- what this sentence is really saying is safety is actually, whether or not -- I would actually say we agreed that other people could probably put together an argument that one or the other IOM six domains was as important as safety.

But we said, "Okay, well, let's just assume it's really important. Actually measuring it is very hard." And so -- then that's what we said we're really dealing with in this paper.

Q. Okay. In the second column on this same page, the second paragraph that begins in that column starts, "For the systematic review of safety studies."

A. Uh-huh.

Q. And am I correct that this group essentially commissioned an independent systematic review of safety studies?

A. Yes.

Page 191

Q. And it describes -- a few lines down it says, quote, "Only prospective randomized double-blind studies reported as full-text articles published in English were included." And I'm not going to ask you again about blinding and randomizing.

Why did you consider it appropriate to restrict the search only to articles published in English?

A. First off, I personally did not make decisions about this on my own. I was very much in the center of -- I'm really a middle person here of a very large group that was making decisions about what we were going to do as a group.

But there was a feeling, at least across all of sedation, procedural sedation and anesthesia, that you could get -- what we needed to get to you could get from randomized controlled trials.

And -- so, again, we made that decision that that's how we are going to do this particular systematic review.

Q. Sorry. My question was focused only on the issue of language, and that was --

A. Oh, the English?

Page 192

Q. And maybe it could be -- we can focus on this article or not. Let me ask more general question.

In your experience, is it commonly the case that systematic review searches are limited to articles published in English in the field of medicine?

MS. LEVI: Object as to form.

A. So my own personal experience has been that we always think about should we include other languages, and then we make a tactical decision not to.

Q. And is there a reason why it is generally accepted in the field as adequate to search only English language materials?

MS. LEVI: Object as to form.

A. I think there's actually always a little bit of a discomfort with the fact that we're limiting it just to English and that -- for example, there are billions of people that live in China and India, and we're not including any medical literature that comes out of those places, which doesn't feel particularly comfortable. But there's just an economy of effort that you have to work

Page 193

with, and...

Q. Is it also the case that, in many cases, science from countries that -- where the native tongue is other than English are nevertheless published in English?

A. Not necessarily.

Q. I didn't say "necessarily." I said, is it often the case?

MS. LEVI: Object as to form.

A. I don't actually know. I don't know.

Q. All right.

You mentioned India. Do you have reason to believe that important medical science coming out of India is published in any language other than English?

A. I have no idea.

Q. Okay. There's a lot of people there, but...

Let's go back, if we could, to the AGREE document, Exhibit 2, and I want to take you to Page 24.

There, at the top, the heading is, under "Rigour of Development," quote, "The health benefits, side effects, and risks have been

Page 194

considered in formulating the recommendations," close quote.

Do you see that?

A. Yes.

Q. And do you agree that, before you relied on a clinical practice guideline, you would want to have good confidence that those who developed it had considered not just benefits but also side effects and risks in formulating their recommendations?

MS. LEVI: Object as to form.

A. I mean, I think it's pretty -- yeah, it's pretty normal to think about all of that and to assume it's been thought about.

Q. Again, that's not what I asked.

A. Okay.

Q. I said, before you rely on a clinical practice guideline, would you want to have good comfort that the team that developed it had considered not just benefits of a procedure or treatment but also the side effects and risks?

MS. LEVI: Object as to form.

A. So when I personally evaluate -- like, look at a guideline, I want to feel comfortable that they have done that.

Page 195

Q. Thank you.

Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed."

So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed?

MS. LEVI: Object as to form.

A. So are we talking about what I want to see, or we talking what this scale's about?

Q. We're talking about what you want to see.

A. So I don't know that I -- if I'm smart enough that I'm looking carefully enough at guidelines to be able to say, "Oh, I evaluated that guideline because they gave me some evidence that they thought about things." Again, I'm sort of

Page 196

assuming that people are thinking about health benefits, side effects.

I think -- well, I'll stop there.

Q. You testified earlier that there are a number of guidelines out there in the world that are not well done and perhaps not reliable, correct?

A. Yes.

Q. And so my question for you is, before you rely on a guideline, do you want to see, in its text, evidence that those who prepared it have considered side effects and risks?

MS. LEVI: Object as to form.

A. I don't think, when I go just in an informal way to look at a guideline for guidance on what to do, that I am looking specifically to see whether they -- what evidence that they've looked at risks and benefits. That's not -- I'm not able to be that granular at that moment that I need the guideline.

Q. Fair enough. And so now let me take us to the next step.

Would you agree that, at least according to the AGREE II principles, that rigorous guidelines should, on their face, show evidence that the

Page 197

authors considered side effects and risks, as well as benefits, in connection with any particular recommendation?

MS. LEVI: Object as to form.

A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has -- you feel comfortable that that evidence is there.

And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to -- most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence.

And, again, if you systematically look, you'll be able to pick where a particular guideline is in that.

Q. At the bottom of the page is a section that says, "How to Rate." Do you see that?

A. Uh-huh.

Q. So, again, this is structure that I know you testified earlier that your team used it as guidance for how to do it?

A. Right.

Page 198

Q. It's structured for somebody who's looking at guidelines to rate them; am I correct?
A. Yes.
Q. And here, to inform the rater's decision between, as you said, a spectrum from a weak 1 to a strong 7, one of the items is "Reporting of the balance/trade-off between benefits and harms/side effects/risks."
Do you see that?
A. Yes.
Q. So you would agree with me that a set of guidelines that rates strongly on this aspect of rigour of development will in fact report in writing the balance or trade-off between benefits and risks or harms that the drafters have considered?
MS. LEVI: Object as to form.
A. So, I mean, again, this is a subjective reading that you're going to use on whether I think a particular guideline has done this.
And to be honest, in the context, it's not just did they do it, but did they well write it, is it clear and concise, is it -- you know, they're sort of telling you all these ways you can think about what was written. Yes.

Page 199

Q. There's many ways it could be written.
My question for you was, do you agree, based on either this discussion of how to rate with regard to Item 11 of the Rigour of Development, that a guideline that rates "strongly" on this particular point will be one which, perhaps among other things, actually reports how the authors evaluated the balance or trade-off between benefits and harms?
MS. LEVI: Object as to form.
A. I would agree, if you are giving a "strongly agree" rating of a guideline on this Number 11, that you have -- it would be able to meet these particular rating guidelines.
MR. BROOKS: Let me ask the reporter to mark as Exhibit 17 an article dated 2013, first author Zitomersky, with Dr. Lightdale as an internal author, entitled "Risk Factors, Morbidity, and Treatment of Thrombosis in Children and Young Adults."
(Document marked as Lightdale Exhibit 17 for identification)
Q. Dr. Lightdale, I'm going to guess that this is an article that you haven't read recently.
A. No, I haven't read this one recently.

Page 200

Q. I acknowledge that it's eleven years old. I acknowledge that you're an internal author, neither the lead nor the final.
Am I correct that the question that was being addressed, however, is how serious is the risk of thromboembolic events for children who are hospitalized with inflammatory bowel disease?
A. Yes.
Q. And therefore, is it appropriate to take prophylactic measures to prevent thromboembolic events in the case of children?
A. Yes.
Q. What is a thromboembolic event, if I'm saying that correctly?
A. You're saying it great. It's a stroke.
Q. Is there anything else that falls within the category of a thromboembolic event?
A. Sure. Any blood clot. So it could be, you know -- most of them, unfortunately, are going to predispose to stroke, but you worry about venous thromboemboli or, you know, DVT, deep venous thromboses, pulmonary emboli.
Q. All these, very serious medical occurrences?

Page 201

A. Blood clots, yes.
Q. Okay. Just so I'm clear -- I know that we're stating things -- am I correct that, categorically, thromboembolic events are considered to pose a risk of serious harm?
A. Yes.
Q. And, indeed, if we turn to Page 344, under "Results" at the bottom, in the first column it states that "Of 532 patients" -- and correct me if I'm wrong, these are all minors that were subject to this study, right?
A. Children, yes.
Q. Of 532 patients who were admitted with inflammatory bowel disease, almost 2 percent suffered thromboembolic events, correct?
A. Yes.
Q. And that's during their period of hospitalization?
A. These were all during the hospitalization, yeah.
Q. Okay. And that's far above the rate you would expect among normal, healthy children, correct?
A. Yes.

Page 202

Q. And in the second column of that same page, it says that four of the 10 had cerebrovascular thrombosis, which is to say a stroke; am I correct?
A. Correct.
Q. One of which resulted in permanent cognitive defects, right?
A. Yes.
Q. And hemiparesis means partial paralysis?
A. Yes.
Q. Okay. Very serious.
One of those four patients required brain surgery? Is that what intracranial vascular surgery is?
A. I believe so.
THE WITNESS: Sorry, I will not --
MS. LEVI: You should make sure you answer his questions, and if you need to review it, take the time to do that.
THE WITNESS: Yeah.
A. Well, in full disclosure, I don't --
MS. LEVI: There's only one medical expert in this room, as far as I can tell.
A. Yeah, so what I can tell you is we described it as intracranial vascular surgery. So I

Page 203

don't know if it was catheterization.
I don't remember the patient. This was a long time ago.
Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not?
A. Not necessarily, but I'm not a brain surgeon.
MS. LEVI: I object to the form of that question.
Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general -- in general among children suffering from inflammatory bowel disease?
MS. LEVI: Object as to form.
A. Yeah, this is a single study retrospective review of our population at our hospital.
Q. And am I correct that that very small sample size can raise questions and concerns, but it can't really answer questions?
MS. LEVI: Object as to form.
A. I think -- it was -- it's an important

Page 204

retrospective review and contributes to the literature of these type of retrospective reviews.
I think it can answer some questions. But it also -- it's limited because it's a retrospective review at a single center.
Q. It raised enough concerns or questions that, based only on this small study, Boston Children's Hospital changed its practices with regard to children admitted with inflammatory bowel disease, correct?
A. Yeah. We made a decision to do that.
Q. Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, if the best available evidence indicated that that treatment increased the long-term risk of thromboembolic events in neonatals by 20 percent, you would consider that to be an adverse effect that needed to be given serious weight in the treatment decision, would you not?
MS. LEVI: Object as to form.
A. Not necessarily. I'd need to know a lot more about what you're just explaining. I mean...
Q. I'm going to ask the reporter to read the

Page 205

question back and see if you have a more precise answer.
THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" --
MR. BROOKS: Let me re-ask it myself.
Q. Dr. Lightdale, in weighing the risks and benefits of a treatment -- we'll stay abstract -- of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not?
MS. LEVI: Object as to form.
A. To me that's just too abstract. Like, I need to understand what we're comparing it to and what the non-treated group looks like, and also why are we treating.
So I don't know that you can answer that question so -- like, I can't give a specific answer to that.

Page 206

Q. You cannot answer the question whether a 20 percent increase in risk of thromboembolic events or strokes is an adverse effect that you would need to at least give serious weight to?

MS. LEVI: I'm going to object as to form, and also it's a re-characterization of the question.

You can answer it, if you can.

A. I mean, I think that when you do clinical studies, you're looking at complications. And so you want to understand what are the safety events, and you're going to categorize them. And then you're going to take that into account as you look at everything.

It's just -- it's too -- I think to just go after throm -- I mean, I don't know that I can answer the question more than that, is the bottom line. I just would need a lot more context around it. So...

Q. If a treatment resulted in 40 percent higher risk of thromboembolic events in the treated population, as compared to the untreated population, would you consider that an adverse effect that would need to be given serious weight in the cost/benefit analysis of a treatment for a condition that was not

Page 207

immediately life threatening?

MS. LEVI: Object as to form.

A. I think all complications need to be brought into the safety/benefit discussion of any treatment.

Q. * If a treatment for a child that you were considering -- if the best available evidence suggested that that treatment would have a lasting negative effect on the memory and learning capability of that child, am I correct that you would consider that to be a very serious harm as you weighed the harms and benefits of treatments?

MS. LEVI: Object as to form.

A. I would agree that you have to think about all complications and that you want to be transparent about them and understand them and weigh them.

Q. I didn't ask about all of them.

MR. BROOKS: I ask the reporter to read back the question.

(* Question read)

MS. LEVI: Preserving my objection for the record on rereading.

A. I mean, I would say, thinking about long-

Page 208

term complications, like a lasting effect on memory is one of the complications I would want to be factoring in to my thinking about whatever we're measuring.

Q. And you're not willing to say, as you sit here today, Dr. Lightdale, that a long-term effect on that child's cognitive capabilities is a very serious negative effect?

MS. LEVI: Object as to form.

A. It's still too abstract, the way we're being asked this.

Q. Do you have any familiarity or general familiarity with the IQ scale?

A. IQ?

Q. Yeah.

A. Only, like, to talk about IQ.

Q. Well, for instance, do you have a notion of the cognitive level of somebody who has an IQ measured at 80?

A. That is -- you are profoundly not high IQ.

Q. And -- do any of the conditions that you as a professional treat and any of -- or any of the treatments that you as a professional are involved in raise any risk of harm to a child's cognitive

Page 209

capabilities?

MS. LEVI: Object as to form.

A. Not directly. So -- I mean, not that I know of.

I think that we worry about side effects. I study sedation, so I worry about, you know, that's going to potentially depress somebody's neurocognitive potential and have an effect. I worry about sedation. I worry about -- sure, I'm worried about strokes in kids.

Q. Right. If a treatment that you were involved in or a clinical situation that you were involved in involved a risk of significant loss of cognitive capability to the child, am I correct that you would consider that to be an important risk, for instance, to disclose to parents?

MS. LEVI: Object as to form.

A. I think that would be an important risk I would disclose to parents.

Q. And if a guideline you were developing involved a therapy which the best evidence suggested posed some risk of lasting cognitive impairment, you would expect to see that disclosed in the guideline, would you not?

Page 210

MS. LEVI: Object as to form.
A. Not necessarily in the guideline if it's some risk. I need to understand just how much risk. And then -- again, I believe in guidelines I trust and trustworthiness of guidelines. So I assume it would be covered.
Q. Do you know who Marci Bowers is?
A. (Shakes head)
That was "No." Sorry.
MS. LEVI: You have to say it audibly.
THE WITNESS: Yes. I apologize.
MS. LEVI: But if you need a break --
THE WITNESS: I was waiting to see if anyone told me to say "No."
MS. LEVI: Do you --
THE WITNESS: I'm okay.
MS. LEVI: Are you sure?
THE WITNESS: Yes, I think so.
MS. LEVI: You should take a break when you need it.
MR. BROOKS: We're going to be done shortly. Normally I offer breaks, but we're going to be done shortly.
MS. LEVI: Okay.

Page 211

BY MR. BROOKS:
Q. Do you agree with me that if a treatment recommended in a set of clinical guidelines involves a significant risk of permanent loss -- let me start again.
Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child?
MS. LEVI: Object as to form.
A. So -- probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies.
Q. And in that context, it's recognized as a serious adverse effect; am I correct?
A. Again, some -- I can think of treatments I know of where this would be something you have to talk about with the families. So...
MS. LEVI: I need a break.
MR. BROOKS: Fine. Pardon me.
(Recess)

Page 212

BY MR. BROOKS:
Q. Dr. Lightdale, let me ask you to pick up Exhibit 17 again, the "Risk Factors" document.
A. Yes.
Q. And I want to clear up one thing. And, again, I'm not trying to trick you with memory tests.
You said more than once that this was about children, and if you turn to Page 345, there's a list at the top of the 10 subjects who suffered thromboembolic events, and all but one of them are older than 10, and some of them are in their younger 20s.
I just wanted to call your attention to that and to clarify for the record that am I correct that the patients covered in this study were, for the most part, teens or very young adults?
A. Yeah, this was -- yes. This was a single-center study. And actually I saw somewhere in it that we had -- the age range was 8 to 23, I think.
Q. Okay. And given that there were just 10 patients who had thromboembolic events -- this is going to be kind of a terminology question -- is

Page 213

this what one would describe as anecdotal evidence, or is it -- kind of rise to the level beyond that?
MS. LEVI: Object to the form.
A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital.
Q. Of a cohort?
A. It's a cohort study.
Q. Retrospective cohort study?
A. Uh-huh.
Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would -- should and would disclose that risk as part of the discussion of risks and benefits?
MS. LEVI: Object as to form.
A. I'm just finding the questions too abstract. There are so many things you need to look at, and so I can't just hear one outcome. I sort of have to understand who is it compared to, and, you

Page 214

know -- whatever. There's just a lot more details. Like, what were the other outcomes? What exactly were we treating? It's almost hard to answer this in the abstract. So...

Q. If -- let me show you a document.

MR. BROOKS: Let me ask the reporter to mark as Exhibit 18 an article from 1922 -- pardon me, 2022 entitled "The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence," by Michael Biggs.

(Document marked as Lightdale Exhibit 18 for identification)

Q. Dr. Lightdale, can I say with some confidence you haven't seen this one?

A. I definitely have not.

Q. And let me take you in this document to Page -- I want to take you to Page 12. At the very bottom of Page 12 is a paragraph that begins, "Even less is known about the effects of puberty suppression on sexual functioning." That's the topic sentence.

And then you can turn over the page. Then there's going to be a quote from Marci Bowers. Let me make a representation to you who Marci Bowers is.

Page 215

She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties."

And the quote here is, quote, "Every single child... who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero."

Now, that's not a study. That's, what shall we say, expert opinion, comment.

My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty blockers on minors would disclose that risk and discuss how it had been weighed by the team in their cost/benefit analysis?

MS. LEVI: Object as to form.

A. This is just so outside my own scope of practice and knowledge. So I'm just in an area that I know nothing about and have no context. And

Page 216

honestly you're asking the question in ways that I'm not sure what I'm answering. So I'd prefer not to answer.

Q. What about --

MS. LEVI: If you can't answer, you can say you can't answer.

Q. What about my question is unclear to you?

A. Honestly, I'm not sure if you're -- I'm not sure if you're asking for me, like, my reaction, or -- you know, there's a lot of ifs in there. So I actually don't understand the data in order to be able to make any sort of, you know, useful statement.

Q. Dr. Lightdale, you've offered opinions that WPATH, in its preparation of their clinical practice guidelines, were, quote, exemplary, right?

MS. LEVI: Answer a question if he's asked one.

MR. BROOKS: I have asked one.

A. I gave an opinion that I thought the process that they describe on their website looks like what you would want a process to look like.

Q. Am I correct that you have not offered and have not formed any opinion that WPATH's SOC-8 was

Page 217

in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines?

MS. LEVI: Object as to form.

A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So...

Q. And you have not formed any opinion as to -- you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines?

MS. LEVI: Object as to form.

A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous, transparent and well thought out; that they put up a process that they were -- that they say that they followed. That's what I can form my opinion on.

Q. And the flip side of that is, you don't have the information you would need to form an opinion as to whether they actually followed the process described in the methodology; am I correct?

A. Correct. Yes.
MR. BROOKS: I have no further questions for the witness.
MS. LEVI: Okay. The witness will read and sign.
(Whereupon the deposition was concluded at 3:15 p.m.)

C E R T I F I C A T E

I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony.

Dated at ___________, this ____ day of _________, 2023.

____

* * * * *

SUGGESTED CORRECTIONS

RE: Brianna Boe, et al., etc., vs.
Hon. Steve Marshall, etc., et al.

WITNESS: Jenifer Lightdale, M.D. , Vol. I

The above-named witness wishes to make the following changes to the testimony as originally given:

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COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness.

I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto or financially interested in the action.

Under Federal Rule 30:

X Reading and Signing was requested

Reading and Signing was waived

Reading and Signing was not requested.

In witness whereof, I have hereunto set my hand and affixed my notarial seal this 14th day of May, 2023.

Carol H. Kusinitz

Notary Public

Commission expires 5/20/27

To: Jennifer Levi, Esq.
Re: Signature of Deponent CONF Jenifer Lightdale, M.D.
Date Errata due back at our offices: 30 days

Greetings:

This deposition has been requested for read and sign by the deponent. It is the deponent's responsibility to review the transcript, noting any changes or corrections on the attached PDF Errata. The deponent may fill out the Errata electronically or print and fill out manually.

Once the Errata is signed by the deponent and notarized, please mail it to the offices of Veritext (below).

When the signed Errata is returned to us, we will seal and forward to the taking attorney to file with the original transcript. We will also send copies of the Errata to all ordering parties.

If the signed Errata is not returned within the time above, the original transcript may be filed with the court without the signature of the deponent.

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ERRATA for ASSIGNMENT #6671430

I, the undersigned, do hereby certify that I have read the transcript of my testimony, and that

___ There are no changes noted.

___ The following changes are noted:

Pursuant to Civil Procedure, Rule 30. ALA. CODE § 5-30(e) (2017). Rule 30(e) states any changes in form or substance which you desire to make to your testimony shall be entered upon the deposition with a statement of the reasons given for making them. To assist you in making any such corrections, please use the form below. If additional pages are necessary, please furnish same and attach.

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DEPONENT'S SIGNATURE

Sworn to and subscribed before me this ___ day of

_____, _____.

_____

NOTARY PUBLIC / My Commission Expires:_____